National Guidelines for
Biosafety and Biosecurity in the Medical Laboratories

IEDCR

Institute of Epidemiology, Disease Control & Research (IEDCR)
Directorate General of Health Services
Government of the People's Republic of Bangladesh

National Guidelines for Biosafety and Biosecurity in the Medical Laboratories

Recommended for all medical laboratories in Bangladesh

Technical support: Centers for Disease Control and Prevention, USA

Institute of Epidemiology, Disease Control & Research (IEDCR)

National Guidelines for Biosafety and Biosecurity in the Medical Laboratories

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First Edition: June, 2019

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Published by:
Institute of Epidemiology, Disease Control and Research
Mohakhali, Dhaka-1212
Bangladesh

Printed By:
Step Communications
House# 26, Road# 02, Block# F, Bonani, Dhaka-1213
Bangladesh

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জাহিদ মালেক, এমপি
মন্ত্রী
স্বাস্থ্য পরিবার কল্যাণ মন্ত্রণালয়
গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

Message

I am pleased to learn that the 'National Guidelines for Biosafety and Biosecurity in the Medical Laboratories of Bangladesh' is being published. All the medical laboratories of Bangladesh will now have a guideline to use for their day to day work in the laboratory. This guideline will also be helpful for biosafety and biosecurity of diagnostic laboratories also. This will help in securing the safety of the personnel working in the laboratories. The security of the microorganisms preserved in the laboratories will also be ensured. Government of Bangladesh is committed to achieve the highest level of biosafety and biosecurity in the public health and diagnostic laboratories.

I would like to thank Institute of Epidemiology, Disease Control & Research (IEDCR) for their success in developing this national guideline. I also thank Centre for Disease Control and Prevention (CDC, USA) for their technical assistance.

Joy Bangla, Joy Bangabandhu
Long live Bangladesh.

Zahid Maleque

Director General of Health Services

Message

I am happy to learn that we are taking an important step to ensure improved biosafety and biosecurity of public health laboratories. Recntly we have advanced from a least developed country to a developing cuntry. We will also be able to upgrade from a high disease burden country to a low disease burden country. We have successfully eliminated small pox, polio; we have controlled malaria, cholera. And certainly we will be successful to improve our biosafety and biosecurity in the medical laboratories.

I fell honored to become a witness of this great achievement of our health sector to publish the "National Guidelines for Biosafety and Biosecurity in the Medical Laboratories of Bangladesh". This huge task has improved our capacity to a new height. I thank the IEDCR team and the panel of contributors for this commendable feat. Now, we have to institutionalize this guideline, for the biosafety and biosecurity of the medical laboratories.

I thank all personnel related to this guideline development. Other countries will also be benefitted from this guideline. I also thank Centers for Disease Control and Prevention (CDC, USA), Bangladesh Country Office for their all-out support to develop this guideline.

Thank you

Professor Dr. Abul Kalam Azad

Foreword

The critical aspects of biosafety and biosecurity have been in the spotlight in recent years, especially when throughout the past few years, the world has been experiencing an emergence of serious biological threats. From SARS to H5Nl avian flu, anthrax, salmonella etc. these threats have demanded action. There have also been increased international efforts to improve awareness of safe practices, thereby resulting in decreased risk of acquisition of deadly pathogens or accidental release of a biological agent, and increased safety of laboratory workers. The laboratory workers are exposed to potential health risks while working with different pathogens. The World Health Organization has simply defines biosafety as "working safely," and laboratory biosecurity as "keeping the working secure." Biosafety and biosecurity are essential pillars of global health security.

Bangladesh needs to strengthen the biosafety and biosecurity of the medical laboratories. In order to assist different medical laboratories in ensuring biosafety and biosecurity we have developed "National Guidelines for Biosafety and Biosecurity in the Medical Laboratories of Bangladesh". This guideline has been aimed to provide guidance to the laboratory personnel so that they can ensure their safety as well as laboratory-related security of the microorganisms.

The biosafety and biosecurity core committee members along with the resource persons from different government, nongovernment medical colleges and hospitals contributed to the development of the "National Guidelines for Biosafety and Biosecurity in the Medical Laboratories of Bangladesh". This guideline is intended for all the medical laboratories of Bangladesh. I believe this guideline will help in improving the biosafety and biosecurity of the medical laboratories.

I like to take this opportunity to give my sincerest thanks and gratitude to Mr. Zahid Maleque,

MP, Honourable Minister for Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh for continuous encouragement. I like to extend my gratefulness to Professor Dr Abul Kalam Azad, Director General of Health Services for his guidance in developing this guideline. I also like to thank all the contributors who shared their valuable time and knowledge. I sincerely acknowledge the efforts of IEDCR personnel especially the members of Biosafety and Biosecurity sub-committee. Finally, I thank US-CDC for technical support.

Prof. Dr. Meerjady Sabrina Flora

Director, IEDCR

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List of Abbreviations

APHL	Association of Public Health Laboratories
BBCC	Biosafety and Biosecurity Coordination Committee
BITID	Bangladesh Institute of Tropical and Infectious Disease
BSCC	Biosafety and Biosecurity Core Committee
BSC	Biological Safety Cabinet
BSL	Biosafety Level
BSO	Biosafety Officer
CDC	Centers for Disease Control and Prevention (USA)
CSDS	Chemical Safety Data Sheet
GCLP	Good Clinical Laboratory Practice
GLP	Good Laboratory Practice
GMO	Genetically Modified Organisms
GMT	Good Microbiological Techniques
HBV	Hepatitis B Virus
HEPA	High Efficiency Particulate Air Conditioning
HVAC	Heating, Ventilation and Air Conditioning
IBC	Institutional Biosafety Committee
IBO	Institutional Biosafety Officer
IEDCR	Institute of Epidemiology, Disease Control & Research
LAI	Laboratory Acquired Infection
LMO	Living Modified Organism
MOHFW	Ministry of Health and Family Welfare
MSDS	Material Safety Data Sheet
PPE	Personal Protective Equipment
QC	Quality Control
SARS	Severe Acute Respiratory Syndrome
SOP	Standard Operating Procedure
VBM	Valuable Biological Material
WHA	World Health Assembly
WHO	World Health Organization

Chapter 1: INTRODUCTION

1.1 Background

Currently, biosafety and biosecurity are the most important issues in the laboratories worldwide. In the fifty-eighth World Health Assembly, the importance of integrated approach for enhancement of laboratory biosafety, including containment of microbiological agents and toxins, promoting global public health, was discussed and the member states were requested to implement biosafety programs in the laboratories of their respective countries. The importance of biosafety becames more evident after reviewing few of the reports on laboratory acquired infections (LAIs). In one of the largest report in 1976, it was found that 4079 LAIs were due to 159 agents with at least 173 deaths. In 2002–2004, 33% of laboratories reported the occurrence of at least one LAI.

In one study, the common LAIs were due to Shigella, Salmonella, Brucella species, *Staphylococcus aureus, Neisseria meningitidis, Escherichia coli* O157:H7, Coccidioides species and *Clostridium difficile*. Although reports are not available, other potentially infectious microorganisms, including Hepatitis B virus, Hepatitis C virus, laboratory strains of viruses and fungi are supposed to be acquired from the laboratory. LAIs in Bangladesh have not yet been reported. However, it is presumed that there might be many cases of LAIs considering the current inadequate biosafety measures. Bangladesh has a well established infrastructure of health care delivery system, where laboratory services have been running from primary (sub district hospital / Upazill Health Complex) to tertiary level hospitals (Medical College Hospital) as well as specialized institutes. However, no biosafety guidance document including infection prevention and control is currently available for clinical, public health or diagnostic laboratories of Bangladesh.

Although a national biosafety guideline is available in Bangladesh, it has been developed focusing primarily on the genetically modified organisms (GMOs) and living modified organisms (LMOs). Finding the gaps in the above-mentioned guideline for biosafety and biosecurity issues in the diagnostic and public health laboratories in the country, the present guideline has been developed by taking supports from the country level experts in this field.

1.2 Purpose

To ensure biosafety and biosecurity with the aim to reduce acquisition and transmission of laboratory acquired infections and prevent risks of intentional or unintentional release of hazardous microorganisms and/or their products which can affect health safety of the laboratory personnel, community people or the environment.

1.3 Scope

The document provides almost all relevant information on biosafety and biosecurity required to understand at every medical laboratory setting. Further, this guideline will provide specific recommendations regarding how to reduce biosafety and biosecurity related risks, and can be used to assist or guide individuals in the laboratory, in the facility, and in the community to make decisions regarding how to mitigate a risk.

1.4 Users

This guideline is useful to all medical laboratory personnel in Bangladesh handling infectious and/or hazardous materials including biological specimens, microbiological agents and toxins. The laboratory personnel including laboratory experts (bacteriologists, virologists, pathologists, biochemists, immunologists, transfusion medicine experts), medical laboratory technologists, phlebotomists, laboratory attendants, cleaners and all others are directly or indirectly related to the medical laboratories. This document is also applicable for others, who are involved with laboratory management and are related to biosafety and biosecurity issues outside the laboratories.

Chapter 2: BIOLOGICAL SAFETY

All clinical specimens may contain infectious microorganisms including bacteria, viruses, parasites and fungi. Biological safety is, therefore, an important issue during handling of any clinical specimen to protect the laboratory staff and people outside the laboratory from laboratory acquired infections.

2.1 Risk groups of microorganisms

The common microorganisms handled in the diagnostic and public health laboratories have been classified according to their degree of pathogenicity, transmission efficiency to individual level and availability of treatment and preventive measures.

Table 1: Classification of infectious microorganisms by risk group and safety practices (adopted from WHO)

Classification	Characteristics	Significant group members	Recommended Biosafety level (BSL)*	Recommended Practices
Risk Group 1	• No or low individual and community risk • A microorganism that is unlikely to cause human or animal disease	• Micrococcus spp. • Lactobacillus spp.	BSL-1	Good Clinical Laboratory Practice Personal Protective Equipment (Laboratory coat, face mask and gloves)
Risk Group 2	• Moderate individual risk, and low community risk. • A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.	• Dengue virus • Hepatitis B virus (HBV) • Salmonella species • Shigella species • Vibrio cholerae	BSL-2	PPE (Laboratory coat, gloves, goggles or face shields) Good Clinical Laboratory Practices Biohazard sign
Risk Group 3	• High individual risk, low community risk • A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. • Effective treatment and preventive measures are available.	• Mycobacterium tuberculosis • Chikungunya virus • Bacillus anthracis • Rickettsia rickettsii	BSL-3	Standard PPE must be worn, and respirators might be required
Risk Group 4	• High individual and community risk • Pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. • Effective treatment and preventive measures are not usually available.	• Ebola virus • Nipah virus • SARS CoV-2	BSL-4	Appropriate PPE from prior BSL levels, as well as a full body, air supplied, positive pressure suit.

* Details of Biosafety level (BSL) is given in Chapter 3.
Note: Examples of the microorganisms under different risk groups are enlisted in Appendix 1

2.2 Risk assessment

Risk assessment for biosafety and biosecurity is a process by which status of a medical laboratory related to infectious microorganisms including safety practices of the laboratory personnel, identification of risk group(s) of the microorganisms handling in the laboratory, as well as quantity and type of biosafety equipment available in the laboratory is assessed. All the laboratories should be assessed by the assigned Biosafety Officer (BSO) of the corresponding laboratory annually and whenever indicated by using the appropriate "Laboratory Biological Risk Assessment Worksheet" (Appendix 7).

2.2.1 Indications for risk assessment

1. All laboratories that handle biological specimens;
2. Assessed laboratories starting any new procedure that involves biological specimen;
3. Any laboratory requesting risk assessment for specific objectives;
4. Any laboratory after facing accidental outbreak/ emergency.

2.2.2 Factors to be considered in risk assessment

1. Degree of pathogenicity of the agent under consideration;
2. Virulence of the microorganism;
3. Infectious dose;
4. Local availability of effective prophylaxis or therapeutic interventions;
5. Potential outcome of exposure;
6. Natural route of infection;
7. Routes of infection, if any, resulting from laboratory manipulations;
8. Stability of the agent in the environment;
9. Concentration of the agent(s)/microorganism(s) and volume of concentrated material to be manipulated;
10. Presence of a suitable host (human and/or animal);
11. Information available from animal studies and reports of laboratory acquired infections or clinical reports;
12. Laboratory activities performing smear/wet preparation, sonication, aerosolization, centrifugation, etc.
13. Any genetic manipulation of the organism.

Chapter 3: SAFETY RULES FOR LABORATORIES

3.1 GOOD CLINICAL LABORATORY PRACTICES

Good Clinical Laboratory Practice (GCLP) is a set of standards that provide guidance on implementing Good Laboratory Practice (GLP) principles for the analysis of biological specimens for various purposes such as diagnosis, surveillance and research. Although the GLP is a quality system that covers the organizational system and the conditions under which non-clinical laboratory works are planned, performed, monitored, recorded and archived; all of these principles must be adopted to the GCLP.

The components of GCLP are:

1. Infrastructure (to plan infrastructure of laboratories according to the services provided by the laboratory);
2. Personnel training and development (availability of a Laboratory Head, a Quality Manager, and a Biosafety Officer, with defined roles and responsibilities of individual staff, have a program for continuous technical training and updating of skills and maintenance of personal files of all technical and non-technical staffs);
3. Equipment (availability of a list of equipment required according to scope, placing equipment suitable and ensuring that it is in good working condition, calibration and validation of equipment before putting it to use and regularly thereafter and training of staff in correct use and calibration of equipment);
4. Reagents and materials (availability of certified standard quality reagents, validating the quality of newly purchased reagents before use and storing of reagents, chemicals and consumables under appropriate environmental conditions with appropriate labels);
5. Specimen collection (usage of the “Specimen collection standrd operating procedure”);
6. Requisition form (usage of the requisition form including all relevant patient information);
7. List of all specimens received;
8. Specimen rejection log (availability of specimen rejection criteria, maintenance of a record of specimens which were rejected prior to analysis and use of specimen rejection statistics to identify training needs for technical staff);
9. Specimen storage;
10. Worksheet for each test/ assay;

11. Reporting test results (ensure authorized signature has verified test results, reporting results clearly, without any errors, specifying measurement procedures when appropriate and units of measurement signed by the authorized signatory, to ensure predetermined turn around times and to ensure the release of results to authorized persons only);

12. Data management;

13. Standard Operating Procedures (SOPs);

14. Laboratory safety (availability of document and practice of laboratory safety policies and procedures and training of all laboratory personnel about the laboratory safety policies and procedures);

15. Ethical (comply with the ethical codes of the laboratory/ institution); and

16. Quality Management System (QMS) encompassing pre-analytic, analytic and post-analytic components of testing.

3.1.1. Do's and don'ts of safe laboratory working practices (adopted from Cheesbrough, 2006)

Do's

- Keeping the SOPs in front so that it can be followed during work.
- Performing every laboratory work following relevant SOP.
- Use of aseptic technique when handling specimens and culture.
- Washing both the hands as per SOP during following five events:
  - i) after handling infectious material;
  - ii) before attending patients;
  - iii) after attending patients and
  - iv) when leaving the laboratory.
  - v) before wearing and removing gloves
- Covering minor wounds with a waterproof dressing, then using gloves over the dressing before handling any infectious materials.
- Wearing appropriate personal protective equipment (PPE) including laboratory coat, face mask, gloves and front-covered shoes when working in the laboratory; i.e the PPE should be covering hair and beard.
- Ensuring that all the PPE are decontaminated correctly; taken off before leaving the laboratory
- Minimizing the creation of aerosols. Centrifuging safely to avoid creating aerosols. Care should be taken in any breakage during centrifugation.

- Managing broken glassware as sharp wastes immediately and safely.
- Using racks to hold specimen containers for avoiding spillages.
- Working neatly and keeping the bench surface free of any unnecessary materials.
- Decontaminating working surfaces at the end of each day's work and immediately after any spillage of biological specimen/ infectious material.
- Reporting immediately to the laboratory Biosafety Officer (BSO) regarding any spillage or other accident involving exposure to biological specimen/ infectious material.
- Managing spills using a spill kit (according to SOP).
- Decontaminating specimens and other infectious materials.
- Properly using and maintaining an autoclave.
- Disposing of laboratory wastes safely.
- Using appropriate disinfectants for decontamination of colour-coded waste bins.
- Using separate puncture-proof, lidded containers for 'sharp wastes'.
- Ensuring technical and auxiliary staff working in the laboratory receives appropriate immunizations (e.g. HBV, Flu, Typhoid vaccines).

Don'ts

- Mouth-pipetting
- Eating, drinking, smoking, storing food, or applying cosmetics in the working area of the laboratory.
- Attending cell phone during work (For any emergency situation, ensure hand hygiene before using the cell phone).
- Practices which could result in needle-stick injury.
- Using chipped or cracked glassware.
- Allowing unnecessary and unauthorized persons to enter the working area of the laboratory.
- Over-filling colour coded waste bins.
- Immunocompromised person working in the laboratory.

3.1.2 Standard precautions

Standard precaution is a simple, consistent and effective approach for infection control by minimizing contact with biological specimens/ infectious agents, utilizing safe work practices and using PPE. Standard precautions include the following key elements:

(1) Hand hygiene

i) Before and after any direct patient contact and between patients, whether or not gloves are worn;

ii) Before and after handling of invasive device

iii) After touching blood, body fluids, secretions, excretions, non-intact skin, and contaminated items, even if gloves are worn;

iv) During patient care, when moving from a contaminated to a clean body site of the patient;

v) After contact with inanimate objects in the immediate vicinity of the patient.

(2) Use of gloves

i) Before any clinical procedure;

ii) When anticipating contact with blood or another body fluid, regardless of the existence of sterile conditions and including contact with non-intact skin and mucous membrane;

iii) Contact with a patient (and his/her immediate surroundings) during contact precautions.

iv) As soon as gloves are torn;

v) When there is an indication for hand hygiene.

(3) Facial protection (eyes, nose and mouth)

Wear a surgical mask (figure 3.2) and eye protection equipment (eye visor/protector, goggles) or a face shield to protect mucous membranes of the eyes, nose and mouth during activities that are likely to generate aerosol, splashes or sprays of blood, body fluids, secretions and excretions.

(4) Use of laboratory coat:

- Wear

  i) Wear laboratory coat to protect skin and prevent soiling of clothing during activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions.

- Remove

  i) Remove soiled laboratory coat as soon as possible carefully following SOP and perform hand hygiene;

  ii) Laboratory coat must be kept inside the laboratory and not to be used / taken outside the laboratory.

(5) Prevention of needle stick and injuries from sharp instruments

Be careful when

i) Handling needles, scalpels and other sharp instruments or devices;

ii) Cleaning used instruments;

iii) Disposing of used needles and other sharp instruments.

(6) Respiratory hygiene and cough etiquette

Persons with respiratory symptoms should apply source control measures;

i) Cover the nose and mouth when coughing/sneezing with tissue or mask, dispose of used tissues and masks and perform hand hygiene after contact with respiratory secretions;

ii) Ensure patients attending laboratory with respiratory infections to wear a face mask.

(7) Environmental cleaning

Use adequate and appropriate procedures for cleaning and disinfection of work surfaces, equipment, environment and other frequently touched surfaces.

(8) Waste management

i) Ensure decontamination (treatment) of any laboratory waste before disposal;

ii) Treat (decontaminate) waste contaminated with blood, body fluids, secretions and excretions as clinical waste, in accordance with local regulations

iii) Human tissues and laboratory waste that is directly associated with specimen processing should also be treated as clinical waste;

iv) Discard disposable items properly.

(9) Patient care equipment

i) Handle equipment soiled with blood, body fluids, secretions and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of pathogens to other patients or the environment;

ii) Clean, disinfect and reprocess reusable equipment appropriately before use for another patient.

Table 2: Indications of hand hygiene with examples

Serial No.	Indications	When	Example
1	Before patient contact	Clean hands before touching a patient	Specimen collection
2	Before an aseptic task	Clean hands immediately before any aseptic task	Aspiration of body fluid collection
3	After body fluid exposure risk	Clean hands immediately after an exposure risk to body fluids (and after glove removal)	Aspiration of body fluid, drawing and manipulating blood, clearing up urine, faeces, handling waste
4	After patient contact	Clean hands after touching a patient	After specimen collection
5	After contact with patient surroundings in a ward/cabin	Clean hands after touching any object or furniture in the patient's immediate surroundings	When collecting specimen from a patient in a ward/cabin

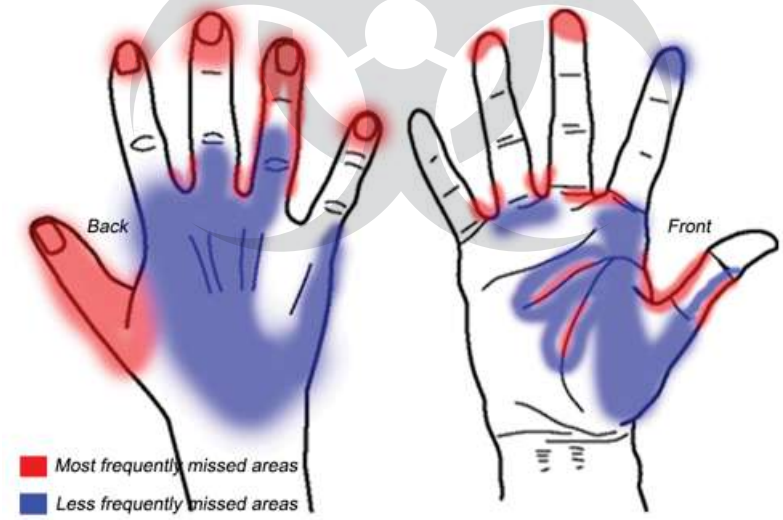


Figure 3.1 Areas missed during hand hygiene

3.1.2.2 Personal protective equipment

Wearing Personal protective equipment is an important factor to ensure personal safety when working in the laboratory. Wearing and removal of the PPE shall be followed strictly by the recommended procedures as described in the SOPs.

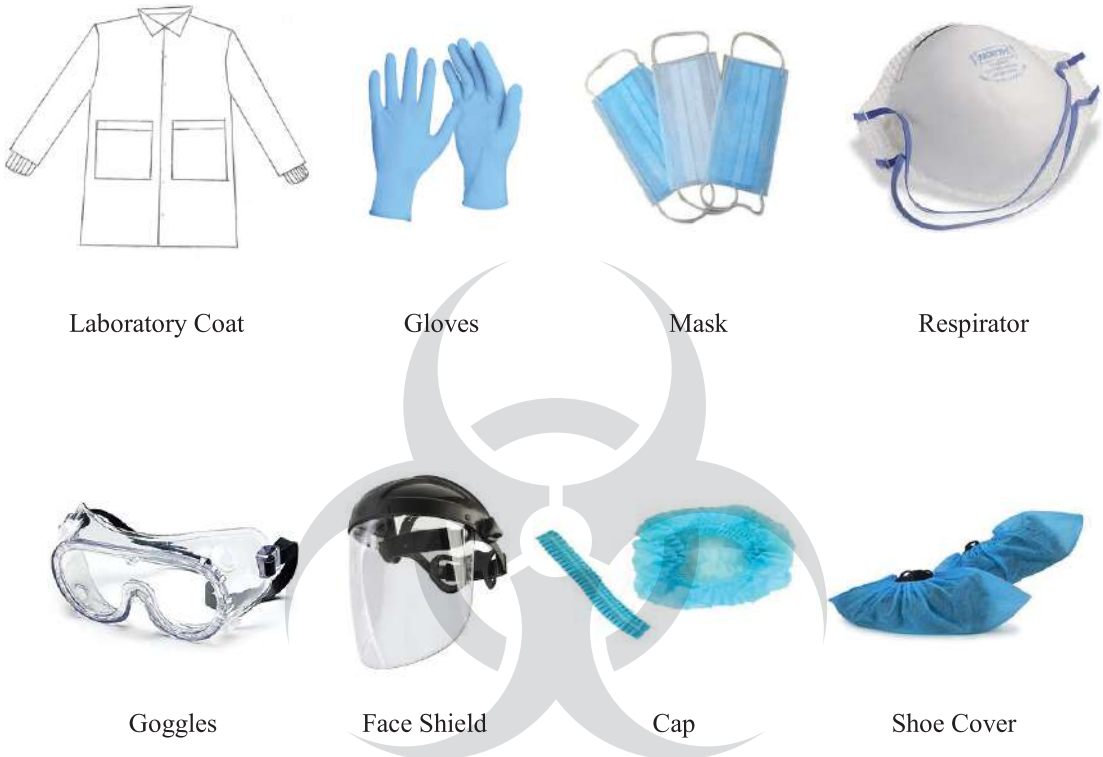


Figure 3.2:Some of the Personal Protective Equipment

Standard Personal Protective Equipment (PPE)
A set of Personal Protective Equipment, which is recommended for standard precautions and applicable for medical laboratory as well as other healthcare services. The set consists of gloves, laboratory coat, mask, cap, goggles, shoe covers/ front covered shoes. Laboratory coat should be full sleeved with a wrist band.

3.1.3. Contact precautions

Following are the recommended precautions for handling patients with known or suspected infections that are transmissible by direct contacts

- Ensure appropriate patient placement during specimen collection so that there is no direct contact with the patient;
- Use personal protective equipment (PPE) appropriately
    - o Wear laboratory coat and gloves for all interactions such as contact with the patient or the patient's environment;
    - o Remove and dispose of contaminated PPE properly and perform hand hygiene after specimen collection.
- Limit transport and movement of patients within the specimen collection area
    - o When transport or movement of the patient is necessary, cover or contain the infected area of the patient's body.
- Use disposable or dedicated patient-care equipment
    - o If common use of equipment for multiple patients is unavoidable, clean and disinfect such equipment before use on another patient.
- Prioritize cleaning and disinfection of the contaminated area of specimen collection room after handling the patients on contact precautions.

3.1.4. Droplet precautions

Following are recommended precautions for handling the patients with known or suspected to be infected with pathogens that are transmitted through respiratory droplets and are generated by the patient during coughing, sneezing or talking:

- Source control: Ensure use of a mask by the patient;
- Ensure appropriate patient placement during specimen collection to avoid transmission of infection to laboratory personnel and other patients;
- Use personal protective equipment (PPE) appropriately including N95 respirator
- Limit transport and movement of patients;

o If transport or movement is necessary, ensure the patient is using a mask and follows Respiratory Hygiene/Cough Etiquette.

3.1.5 Respiratory hygiene / cough etiquette

Respiratory hygiene / cough etiquette is a series of actions to take during coughing or sneezing, which are designed to reduce the spread of respiratory pathogens to others.

It includes the following:

- Cover the mouth and nose with a tissue/a piece of clean, personal clothing during coughing or sneezing;
- Discard the used tissue in a waste bin;
    - For reusable clothing, in-fold the contaminated area of the clothing, which is to be covered by uncontaminated area of the clothing and decontaminate appropriately.
- If tissue/personal clothing is not available, cough or sneeze into the upper sleeve or elbow, not over the hands;
- A facemask can be used to protect others;
- Perform hand hygiene if hands have been contaminated with respiratory secretions.

3.2 Biosafety levels

A biosafety level is the status of a laboratory created by a set of bio-containment precautions required to confine dangerous biological agents in an enclosed laboratory facility. The levels of containment in a laboratory range from the lowest at biosafety level 1 (BSL1) to the highest at level 4 (BSL 4).

3.2.1 Biosafety level 1

Biosafety level 1 (BSL1) laboratories are the basic laboratories which handle microorganisms of risk group 1 (Table1). No special design or equipment is needed but there must be adequate space for laboratory performances.

3.2.1.1 Code of practice

Each laboratory should follow a safety or operations manual that identifies known and potential hazards, and specifies practices and procedures to eliminate or minimize such hazards. Good microbiological techniques (GMTs) are fundamental for laboratory safety.

3.2.1.2 Characteristics (laboratory design and physical requirements)

- Laboratory should have door for access control;
- Laboratory functions can be done in open bench top with sufficient light;
- Biological safety cabinets are not required for handling microorganisms of risk group 1;

- Safety is achieved through following the standard precautions and using appropriate PPEs;
- Laboratory must have a sink for hand washing;
- Laboratory should be designed so that it can be easily cleaned;
- Spaces between benches, cabinets and equipment should be accessible for cleaning;
- Bench top must be impervious to water and resistant to heat, organic solvents, acids, alkalis and other chemicals;
- Chair in the laboratory must be covered with nonporous material so that it can be easily cleaned and decontaminated with appropriate disinfectant;
- Emergency shower and eye wash station should be placed outside the laboratory with easy access for laboratory workers;
- Examples: In Bangladesh, almost all districts and all upazilas level laboratories are BSL1 standard laboratory.

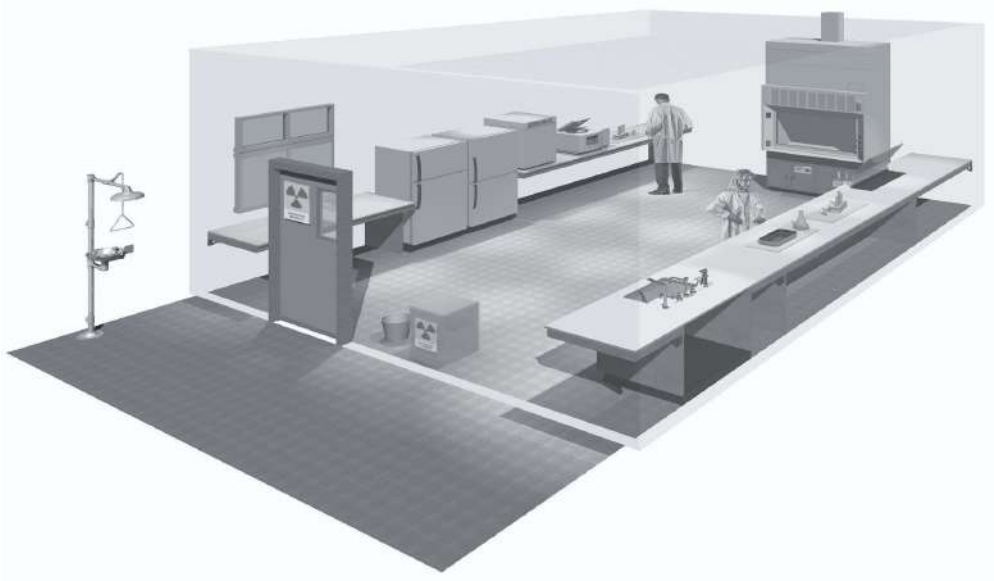


Figure 3.3 Biosafety level 1 laboratory design (WHO, 2004)

3.2.1.3 Personal Protective Equipment for BSL1

1. Laboratory coat must be worn at all times for work in the laboratory; do not take laboratory coat out of laboratory

2. Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials. After completion of laboratory work, gloves should be removed aseptically and hands must then be washed;

3. Safety glasses, face shields or other protective devices must be worn when it is necessary to protect the eyes and face from splashes, impacting objects and sources of artificial ultraviolet radiation;

4. Special containment devices or equipment such as biosefety cabinets are not generally required.

3.2.1.4 Safety measures / practices recommended for BSL1

Appropriate training of the laboratory personnel:

- Hand washing- after handling infectious materials and before leaving the laboratory working areas;
- Mechanical pipetting only (no mouth pipetting allowed);
- Safe handling of sharps (follow SOP);
- Decontamination of all cultures, stocks and other potentially infectious materials before disposal using an effective method (follow SOP);
- Avoidance of splashes or aerosols;
- Daily decontamination of all work surfaces when work is completed;
- Prohibition of food, drink and smoking materials in laboratory setting;
- Prohibition of wearing laboratory clothing, especially laboratory coat, outside the laboratory, e.g, in canteens, seminar / workshops, coffee rooms, offices, libraries, staff rooms and toilets;
- Wearing of closed toe footwear in laboratories;
- No material shall be placed in the mouth (e.g. betel nut, gum, etc.);
- Use adhesive labels or glue for attaching labels.

3.2.2 Biosafety level 2

Biosafety level 2 (BSL 2) laboratories are those which handle microorganisms of risk group 2 and perform some specific tests (e.g. ELISA, PCR) requiring non-infectious materials. All code of practice and physical facilities required for BSL1 are recommended for BSL2 in addition to other specific requirements.

3.2.2.1 Code of practice

Each laboratory should follow a safety manual or operations manual that identifies known and potential hazards, and specifies practices and procedures to eliminate or minimize such hazards. The most important concepts are listed below:

- The international biohazard warning symbol/ sign (Figure 3.4) must be displayed on the doors of the rooms;
- Access to laboratory should be restricted and only authorized persons should be allowed to enter the laboratory working areas;
- Laboratory doors should always be kept closed (self-closing doors with locks preferred).

3.2.2.2 Characteristics (laboratory design and physical requirements) for BSL2

In addition to the design and facilities listed for BSL1:

- In the BSL 2 laboratory, properly maintained and certified biological safety cabinets (BSCs),

Centrifuge machines with sealed rotors or safety cups are essential;

  - BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations;
  - BSCs should be located away from the doors, windows that can be opened;
  - High efficiency particulate air conditioning filtered exhaust air from class II BSC can be recirculated back into the room if it is tested and certified annually;

- There must be hand washing facilities, and decontamination equipment;
- Emergency safety shower and eye wash station should be placed outside the laboratory so that laboratory workers can access them easily;
- Walls, ceilings and floors of the laboratory should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants;
- Floors should be slip-resistant or epoxy coated;
- Examples: In Bangladesh, some medical college laboratories have BSL2 facilities.

Figure 3.4 Biohazard warning sign for laboratory doors

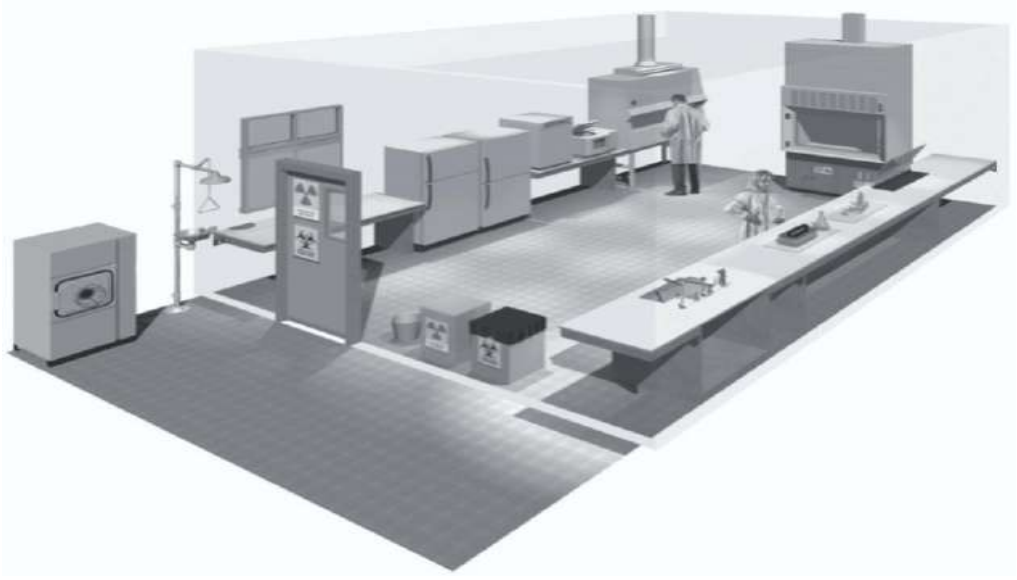


Figure 3.5 Biosafety level 2 laboratory design (WHO, 2004)

3.2.2.3 Personal protective equipment (PPE) for BSL 2

- Laboratory coat must be worn at all times for work in the laboratory;
- Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials;
- After use, gloves should be removed aseptically and hands must then be washed;
- Safety glasses, face shields or other protective devices must be worn when it is necessary to protect the eyes and face from splashes, impacting objects and sources of artificial ultraviolet radiation.

3.2.2.4 Safety measures / practices recommended for BSL2

In addition to recommendations for BSL 1

- The laboratory has self-closing, lockable doors;
- All procedures that can produce aerosols or splashes have to be performed within a biological safety cabinet class II;
- An emergency shower and eye wash station should be readily available outside the laboratory;
- An autoclave or an alternative method of decontamination is available for proper disposals of laboratory waste;
- The laboratory should be kept neat, clean and free of materials that are not pertinent to the work;
- Work surfaces must be decontaminated after any spillage of potentially dangerous material, and at the end of the daily routine activities;
- All contaminated materials, specimens and culture media must be decontaminated before disposal;
- All contaminated containers including culture media plates/bottle/tubes must be decontaminated before cleaning for reuse;
- A spill kit (undiluted bleach, forceps, paper towel, biohazard bags, other PPE) should be available in the laboratory (Figure 11.2)
- Laboratory should be well illuminated.

3.2.2.5 Special practices for BSL2

- All persons entering the laboratory must be advised of potential hazards and meet specific entry/ exit requirements;
- Laboratory personnel must be provided medical surveillance as appropriate and offered available immunization(s);
- Laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and microbiological practices before working with BSL2 agents;
- Incidents that may result in exposure to infectious materials must be immediately evaluated, treated accordingly, documented and reported to the supervisor

3.2.3 Biosafety level 3

Biosafety level 3 (BSL3) laboratories are considered as containment laboratories and handle microorganisms of risk group 3 (Appendix 1) and with large volumes or high concentrations of risk group 2 (Table 1) that pose an increased risk of aerosol spread.

3.2.3.1 Code of practice

The code of practices for basic laboratories, e.g., Biosafety Levels 1 and 2 applies for BSL 3, except where modified as follows:

- The international biohazard warning symbol/ sign (Figure 3.4) must be displayed on the doors of the rooms;
- The name of the laboratory supervisor who controls the access to the laboratories should also be displayed;
- Solid-front or wrap-around gowns, scrub suits, coveralls (front-buttoned standard laboratory coats are unsuitable, as are sleeves that do not fully cover the forearms) recommended.
- Protective clothing worn in the laboratory must be removed before going outside the laboratory, and it must be decontaminated before it is laundered;
- Procedures for all potentially infectious material must be conducted within a biological safety cabinet or other primary containment device;
- Respiratory protective equipment may be necessary for some laboratory procedures.

3.2.3.2 Characteristics (Laboratory Design and Physical Requirements) for BSL3

- The laboratories must be in a separated area within the main building;
    - The access to the laboratory should be through an ante-room (e.g. a double-door entry or basic laboratory of BSL2) with self-closing and interlocking doors so that only one door is open at a time.
- The windows must be closed, sealed and break-resistant;
- The floors, walls and ceilings should be impermeable to water and other liquids;
    - The floor of the laboratory should be slip-resistant or epoxy coated;
- The ventilation should be such that no air is re-circulated in other areas of the building;
    - The air within the laboratory should be filtered, re-conditioned and re-circulated through high efficiency particulate air (HEPA) filter;
    - Installation of heating, ventilation and air-conditioning (HVAC) control system is necessary;
    - Both supply and exhaust air must be HEPA-filtered;
    - All HEPA filters need to be tested and certified annually.
- A ducted air ventilation system is required to provide sustained directional air flow by drawing air into the laboratory from clean area towards potentially contaminated area;
- The biosafety cabinets class II must be away from the walking areas;
- Centrifuge machines with sealed rotors or safety cups are essential;
- There must be hand washing facilities and equipment (e.g. autoclave) for decontamination;
- An emergency safety shower and eye wash station must be readily available.

Example: In Bangladesh, Institute of Epidemiology, Disease Control and Research (IEDCR), Bangladesh In itute of Tropical and Infectious Disease (BITID) and National Tuberculosis Control Program (NTP) in Sylhet have BSL3 standard facilities which require regular certification. None of these laboratories are certified yet.

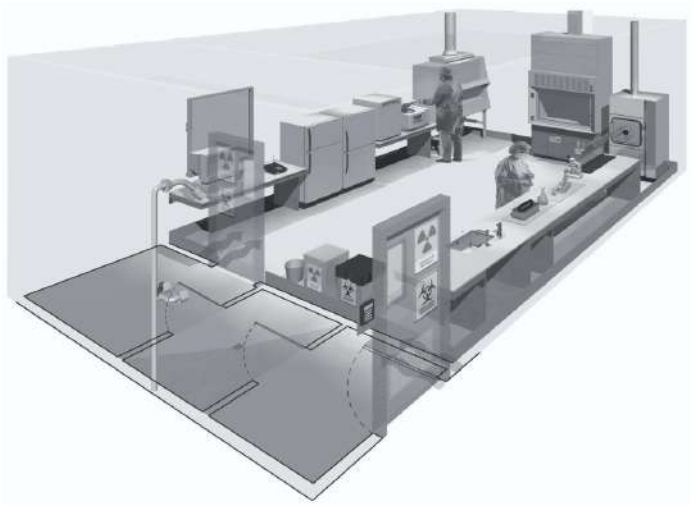


Figure 3.6 Biosafety level 3 laboratory design (WHO, 2004)

Figure 3.7 Eye wash station

Figure 3.8 Eye wash bottle

Figure 3.9 Safety shower with eye-wash station

3.2.3.3 Personal Protective Equipment for BSL 3

- Solid-front or wrap-around gowns, scrub suits, recommended;
    - o Protective clothing is not worn outside the laboratory.
- Eye and face protection devices (goggles, musk, face-shield);
- Head covering;
- Shoe covers or dedicated shoes;
- Respiratory protective equipment may be necessary for some laboratory procedures.

3.2.3.4 Safety practices / measures recommended for BSL3

In addition to recommendations for BSL 1 and 2

- All procedures must be done within the biosafety cabinets;

  Air within the laboratory should be filtered, reconditioned and re-circulated through high efficiency particulate air (HEPA) filter.

3.2.4 Biosafety level 4

Biosafety level 4 (BSL4) laboratories are considered as maximum containment laboratories and handle microorganisms of Risk group 4 (appendix 1). There are two models of BSL4 laboratories: (a) Cabinet laboratory- manipulation of microbial agents must be performed in a class III BSC, (b) Suit laboratory- personnel must wear a positive pressure supplied air protective suit. Both the types of BSL4 laboratories have special engineering and design features to prevent microorganisms from being disseminated into the environment.

3.2.4.1 Code of practice

The code of practice for Biosafety Level 3 also applies except where modified as follows:

- In BSL4 laboratory;
- All clothing and shoes should be changed before entering or exiting from the laboratory;
- All laboratory personnel must be trained in emergency management procedures.

3.2.4.2 Characteristics (laboratory design and physical requirements)

- The BSL4 is a maximum containment laboratory and preferably be located in a different building;

(1) Efficient primary containment system consisting of one or a combination of BSC class III and suit laboratory;

a. To enter into the laboratory, passage through a minimum of two doors is required and a shower with inner and outer changing rooms is necessary;

b. A protective laboratory suit contains self-contained breathing apparatus. Personnel who enter the suit area are required to don a one-piece, positively pressurized, HEPA-filtered, supplied-air-suit;

c. A suit decontamination shower must be provided and used by personnel leaving the containment laboratory area;

d. An appropriate warning system for personnel working in the suit laboratory must be provided for use in the event of mechanical system or air failure.

(2) Controlled access- BSL 4 must be located in a separate building;

a. Entry and exit of personnel and supplies must be through an airlock or pass-through system.

b. On entering, personnel must put on a complete change of clothing and before leaving, they should shower and put on their normal clothing.

(3) Controlled air system- Negative pressure must be maintained in the facility;

a. Both supply and exhaust air must be HEPA-filtered;

b. All HEPA filters need to be tested and certified annually.

(4) Decontamination of effluents- all effluents from the suit area, decontamination chamber, decontamination shower or class III biological safety cabinet must be decontaminated before final discharge;

(5) Sterilization of waste materials- a double-door, pass-through autoclave must be available in the laboratory area;

Example: In Bangladesh, there is no BSL4 standard laboratory

Figure 3.10 Biosafety level 4 suit laboratory design

Figure 3.11: Biosafety level 4 laboratory interior setup (Source: CDC suits, Hazmat suits and gasmasks

3.2.4.3 Personal protective equipment (PPE) for BSL 4

- The personeel must wear appropriate PPE including PPE for BSL 3 as well as a full body, air-supplied, positive pressure suit.

3.2.4.4 Safety practices / measures recommended:

In addition to BSL 1, 2 and 3 recommendations:

- Personnel are required to change clothing before entering and shower before exiting;
- Decontamination of all materials before exiting;
- Personnel must wear appropriate PPE, including PPE for BSL 3 as well as a full body, air-supplied, positive pressure suit;
- A Class III biological safety cabinet;
- The two-person rule should apply, no individual should work alone;
- A complete change of clothing and shoes is required prior to entering and before exiting the laboratory.

Table 3. Summary of all biosafety level's requirements as per WHO recommendation

	BSL 1	BSL 2	BSL 3	BSL 4
Isolation[1] Laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
a) Inward airflow	No	Desirable	Yes	Yes
b) Controlled ventilating system	No	Desirable	Yes	Yes
c) HEPA- filtered air exhaust	No	No	Yes[2]	Yes
Double- door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	-
Anteroom with shower	No	No	Yes[3]	Yes
Effluent treatment	No	No	Yes[3]	Yes
Autoclave:				
a) on site	No	Desirable	Yes	Yes
b) in laboratory room	No	No	Desirable	Yes
c) double -ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personal safety monitoring capability[4]	No	No	Desirable	Yes

[1]Environmental and functional isolation from general traffic.
[2]Dependent on location of exhaust
[3]Dependent on agent(s) used in the laboratory.
[4]For example window, closed- circuit television, two-way communication, etc.

Chapter 4: BIOSAFETY PROGRAM

4.1. Introduction

The health care delivery in Bangladesh follows a tier-wise structure which includes community clinic to tertiary level hospitals, including specialized institutes. Not only in government sector but a huge number of different levels of private laboratories are also running throughout the country. As per this guideline, all laboratories under regulation of Ministry of Health and Family Welfare have to follow Biosafety and Biosecurity (BSBS) programs.

4.2.Biosefety and biosecurity coordination Committee (BBCC)

The BBCC will guide and help in implementation of nationwide BSBS program. This committee will provide support to all institutional biosafety and biosecurity committees. This may consist of 10 members with the Chairperson being the Director Generel, Diroectorate Generel of Health Services (DGHS, Dhaka) Terms of reference for the BBC are given in the appendices (Appendix 9).

4.2.1 Structure of the BBCC (10 members committee)

- Chairperson (Director Generel, Health Services, DGHS, Dhaka);
- Member Secretary (Director, IEDCR) ;
- Members

  Director, Hospital and Clinics, and Head, Quality Improvement System, DGHS.

  Director Disease Control

  Director, National Institute of Laboratory Medicine and Referral Centre (NILMRC)

  Director, Institute of Public Health (IPH)

  Head, Armed Forces Institute of Pathology (AFIP)

  Head, Virology Laboratory, icddr, b, Mohakhali, Dhaka

  Representative of WHO

4.3.The BSBS Core Committee (BSCC)

The BSCC at IEDCR will provide support to all institutional Biosafety and Biosecurity committees regarding assesment of labrotories, monitoring evaluation and training. This may consist of 9 members with the Chairperson being the Director of IEDCR. Terms of reference for the BSCC are given in the appendices (Appendix 9).

4.3.1 Structure of the BSCC (9 members committee)

- Chairperson (Director, IEDCR);
- Co-Chairperson (CSO, Virology) ;
- Coordinator [Biosafety Officer (BSO), (if not available, assigned officer)]
- Members- 6 (1 from each of the departments of Virology, Parasitology, Zoonosis, Microbiology and consultants of Disease Surveillance and BSBS program)

4.4 Institutional Biosafety Committee (IBC)

An institutional Biosafety Committee (IBC) has to be formed, which will be responsible for ensuring the implementation of the policy and guidelines specified in this document. Every institute/facility should have a biosafety committee for the laboratory. The IBC will serve as the focal body for all the BSBS related issues of the institution, including related administrative controls. The IBC should contact BSCC for any locally unresolved issues related to BSBS. Terms of reference for the IBC are given in the appendices (Appendix 9).

It is the responsibility of the laboratory head (in case of multiple laboratories in an institute, Microbiology laboratory head will take the responsibility and other laboratory head(s) will be members in the committee) to form a committee for the laboratory. The committee should meet monthly and will discuss all issues related to biosafety and biosecurity. Each committee may consist of 5-9 members as appropriate.

4.4.1 Structure of the Institutional Biosafety Committees (IBCs)

4.4.1.1 IBC for the Medical College Hospital laboratory (5 -9 members committee)

- Chairperson (Director, Hospital);
- Coordinator (Biosafety Officer, BSO)- (Head, Blood transfusion/ Laboratory Medicine/ Clinical Pathology);
- Members: 2/4/6 (at least one member shall be from Laboratory Medicine department).

4.4.1.2 IBC for the Medical College laboratories (5 -9 members committee):

- Chairperson (Principal, Medical College);
- Coordinator (Biosafety Officer, BSO from department of Microbiology / Virology / Biochemistry);
- Members: 2/4/6 (at least one member shall be from Microbiology department).

4.4.1.3 IBC for the specialized hospital /institution laboratory (5-7 members committee):

- Chairperson (Head, Specialized hospital/institution);
- Coordinator (Biosafety Officer, BSO from Microbiology / Virology / Biochemistry);
- Members: 2/4 (at least one member shall be from Microbiology or allied subject).

4.4.1.4 IBC for the district hospital laboratory (5 -7 members committee):

- Chairperson (Civil Surgeon/ Superintendent of district hospital);
- Coordinator (Biosafety Officer (BSO) Microbiology / Virology / Biochemistry);
- Members: 2/4 (at least one member shall be from Laboratory).

4.4.1.5 IBC for the upazilla health complex laboratory (5 members committee):

- Chairperson (upazilla health and family planning officer);
- Coordinator (Biosafety Officer (BSO) any Medical Officer, other than MO assigned to laboratory);
- Members: 2 (at least one member shall be MO assigned to Laboratory).

4.5 Elements of biosafety program

A Biosafety program shall be in place, with regular monitoring and review, to ensure a safe work environment and practices in the laboratory, encompassing the following elements:

4.5.1 Biological risk assessment;

4.5.2 Provision of biosafety training;

4.5.3 Employee occupational exposure plan;

4.5.4 Assessment of the laboratory for implementation of practices in accordance with safety guideline;

4.5.5 Management of accidents and incidents;

4.5.6 Management of staff health;

4.5.7 Occupational health surveillance;

4.5.8 Monitoring of safety systems;

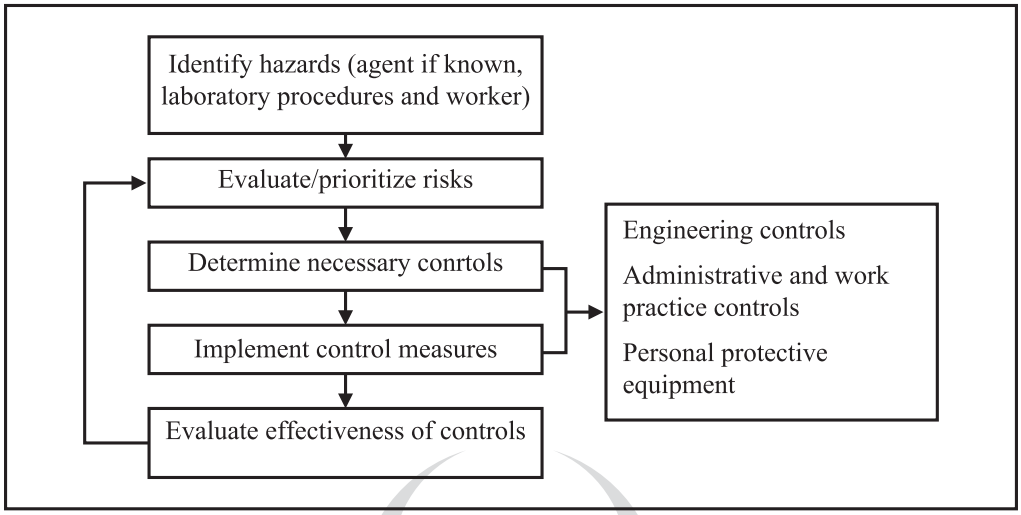
4.5.9 Maintenance of various safety records.

4.5.1 Biological risk

Assessment:

To maintain proper biosafety and biosecurity status in a medical laboratory, a regular risk assessment must be conducted. Risk assessments should be performed by the Institutional Biosafety Officer (IBO), who is familiar with the microorganisms being handled, the equipment and procedures to be employed and the available facilities. The Institutional Biosafety Committee (IBC) is responsible for ensuring that adequate and timely risk assessments are performed, and appropriate equipment and facilities are available to support the safe laboratory works. Risk assessments should be reviewed routinely and revised when necessary, e.g. new data regarding any organism, and a new procedure have been taken in the laboratory, etc. We have developed an Assessment Tool, adopted from the Centers for Disease Control and Prevention, USA (US-CDC) and Association of Public Health Laboratories (APHL), which is attached here in annexure (Annex 11.6). Flow chart for risk assessment is as follows on next page:

Risk assessment process for biological hazards



Based on the above mentioned risk assessment, the IBC shall be able to implement the following activities:

- Identify the laboratory's biosafety level;
- Incorporate/ update use of biosafety equipment, practices and procedures;
- Develop and implement an appropriate biosafety program in the laboratory.

4.5.2 Provision of biosafety training

All staff of a medical laboratory shall be trained to promote correct attitudes and understanding of safe working practices, including personal hygiene, appropriate use of PPE with good laboratory techniques, safe use of equipment, and recognition of hazards, risks and consequences before commencement of practical laboratory work.

To maintain and update staff awareness of the safety implication of changing technology and improvements in safety practices, continuing education and training should be undertaken and documented. Personal training records shall also be kept. For work in BSL 3 or BSL 4 laboratories, more intensive and specialized training should be provided. In addition, staff's experience and competence of safe working practices shall be formally assessed and documented before commencement of a work.

All laboratory personnel and the respective top management shall receive training on the laboratory's biosafety program including

- The potential hazards associated with laboratory activities and practices;
- Procedures intended to avoid exposure to and/or dissemination of infectious material;
- Familiarization with the laboratory's occupational exposure plan. Training and discussion should be with ongoing supervisory observation to ensure staff compliance with the laboratory's safety policies and proper use of PPE. Training shall be conducted as a part of initial training (basic training) and annually thereafter (refresher training) and shall be documented.

4.5.3 Employee occupational exposure control plan

The laboratory shall establish an "Employee Infectious Agent Exposure Control Plan" appropriate for the testing and procedures performed by the laboratory. The plan shall include:

- Immediate notification to the laboratory director or designee of an occupational exposure, or of an employee exhibiting symptoms consistent with an occupational exposure;
- Medical risk assessment;
- Diagnostic testing and treatment, as appropriate;
- Root cause investigation;
- Implementation of corrective action and re-training as necessary;
- The employee exposure control plan should be developed based on the laboratory's infectious agent risk assessment and should take into account the specimen types received and the procedures performed.

4.5.4 Assessment of the laboratory and implementation of the SOPs

The laboratory should periodically be assessed by the IBC as per Laboratory Assessment tool. (Appendix- 6) The IBC will also be responsible for implementation of the Standard Operating Procedures (SOPs).

4.5.5 Management of accidents and incidents

Contingency plans and procedures for accidents and incidents, for example, spillage of pathogens, malfunctioning/non-functioning of BSC, autoclave and other equipments shall be in place as per this guideline. An accident and incident reporting mechanism shall be disseminated among all staffs so that the accidents and incidents could be promptly reported to the IBO and managed accordingly. Preventive measures shall be implemented as well. All accidents and incidents shall be investigated and properly documented along with their corrective and preventive actions. A continuous improvement shall be in place to review and improve the safety program. In cases with potential threat to public health, the management shall take appropriate actions and notify appropriate authority without delay.

Corrective action

The corrective acton shall have a documented procedure for: (i) reviewing NCs; (ii) determining the rootcauses of NCs; (iii) evaluating the need for corrective action to ensure that NCs do not recur; (iv) determining and implementing corrective action needed; (v) recording the results of corrective action taken; and (vi) implementing the effectiveness of corrective action taken.

Preventive action

Preventive action is a proactive process for identifying opportunites for improvement rather than a reaction to the identification of problems or complaints (i.e., non conformations). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analysis and external quality assessment (profeciency testing).

4.5.6 Management of staff health

The management shall take adequate measures to secure health of the laboratory staff. The staff health program shall encompass the following:

- Pre-employment check-up;
- Provision of immunization where indicated;
- Keeping up of baseline sera;
- Medical surveillance to monitor staff sickness through reporting and recording of illness and absence;
- Provision of medical care as necessary;
- Proper record keeping.

4.5.7 Occupational health surveillance

Laboratory related occupational health surveillance is different from monitoring of general health. Health surveillance is an essential process within laboratories, particularly if the laboratory deals with hazardous substance on a regular basis. An effective health surveillance program of a laboratory can play a significant part in the overall control and monitoring of the risks associated with harmful microorganisms. It provides a means of checking whether or not control measures are working effectively, while also monitoring the accuracy of risk assessments.

Occupational health surveillance clearly has a significant role in a laboratory's management of risk exposure. However, the few challenges which can interfere with the health surveillance program should be addressed when designing the program, include:

- Continuous changing of different activities undertaken in a laboratory, with employees encountering different types of potentially hazardous substances that may need different surveillance requirements;
- Some activities during outbreaks, which may have only limited information or guidance on the potential hazards involved;
- The potential of some employees (e.g. cleaning or maintenance workers) usually excluded from the surveillance program.

To overcome such challenges and to ensure legislative and best practice requirements, the laboratory BSO need to ensure systems so that occupational health surveillance management systems are flexible, adaptive and firmly implemented.

4.5.8 Monitoring of safety systems

Examples of elements to be inspected and audited include:

- Training of personnel;
- Monitoring of equipment and facilities;
- Implementation of safe work practices;
- Maintenance of accident records;
- Monitoring of staff health.

4.5.9 Maintenance of various safety records

Maintenance of records are an integral part of the management system for a laboratory. They provide an historical record of the following activities associated with the use of a particular piece of equipment.

- Maintenance of equipment;
- Certification of equipment;
- Any accidents;
- Waste management;
- Training of laboratory personnel

Maintenance records should be kept for at least five years.

Chapter 5: BIOLOGICAL SPECIMEN COLLECTION, PROCESSING, TESTING AND STORAGE

5.1 Introduction

Safe handling of biological specimens is essential to prevent possible spread of infectious diseases to laboratory users and community. All laboratory personnel have the responsibility to fully understand the safety guidelines and must ensure that all safety procedures are strictly followed during collection, processing, testing and storage of biological specimens. The laboratory head/Institutional Bio-safety Officer (BSO) has the responsibility to make sure that all laboratory personnel must complete necessary training before commencement of any laboratory activity.

5.2 General safety guidelines

1. All laboratory personnel shall practice “STANDARD PRECAUTIONS” and "GOOD CLINICAL LABORATORY PRACTICE (GCLP)" in the course of their duties;

2. Both hands must be washed before and after sample collection, processing, storage and testing of biological specimens;

3. The laboratory personnel should use appropriate PPE during collection, processing, storage and testing of biological specimens. This typically includes laboratory coat, front-covered shoes, impervious gloves (such as surgical type gloves), mask and goggles;

4. Additional precautionary measures such as full PPE may be necessary, with specific operations in the laboratory;

5. All PPE must be removed before leaving the laboratory area.

5.3 Safety during collection of specimen

1. All clinical specimens should be considered as bio-hazardous and potentially infectious;

2. Appropriate PPE should be used for collection of specimen;

3. Both hands must be washed before and after sample collection;

4. Gloves should be changed in between collection of each patient’s specimen. Alternatively, gloves may be disinfected by rubbing with 70% alcohol in between collection of specimens from multiple patients;

5. Blood should be collected properly with all aseptic precautions using appropriate disinfectant for the puncture site on patient as well as the phlebotomist;

6. For collection of nasal and throat swabs: Respiratory protection is absolutely mandatory (full face mask or N95 respirator);

7. For collection of Sputum:

- Any coughing patient, who has come to the laboratory, should be asked to cover his or her mouth with a mask or alternatively use tissue or upper sleeve during coughing/sneezing;
- Always collect sputum specimens in outdoors, where the movement of the air will rapidly dilute infectious droplets;

NEVER collect sputum specimens in laboratories, toilets, waiting rooms, reception rooms, or other enclosed spaces.

5.4 Safety during processing of specimen

1. Before processing, specimens should be checked for rejection criteria;
2. For a BSL1 laboratory, a "specimen processing zone" for handling specimens should be designated and should be clearly marked with "Biohazard" warning labels;
3. For BSL 2 and onward levels, all specimens should be processed in a certified Class II or higher Biological Safety Cabinet (BSC) and should follow biological safety practices;
4. Appropriate PPE should be used for the entire operation. Additional precautionary measures such as full PPE may be necessary, with specific procedures in the laboratory;
5. All procedures should be performed carefully to minimize the creation of aerosols or splashes;
6. Centrifugation of specimens should be performed using sealed centrifuge rotors. Whenever possible, the rotors should be unloaded inside a BSC 3;
7. Mouth pipetting is prohibited, use mechanical pipetting devices;
8. Work surfaces shall be decontaminated using appropriate disinfectants at beginning and after completion of any work and after any spillage.

5.5 Safety during test procedures

1. All test procedures should be performed using appropriate PPE according to biosafety levels of the laboratory work.

5.6 Safe storage of biological specimen

1. Storage facilities should be in place for all laboratories;
2. Generally, storage facilities should be locked and have limited access to prevent unauthorized access to the specimens;
3. Reagents and specimens should be stored in separate freezers and refrigerators maintained with temperature logs. If the specimens are required for testing/analysis by other laboratories, the specimens should be stored according to the requirements of that laboratory;
4. Refrigerators and freezers should preferably be located in laboratory dedicated space, not in office space and temperature should be maintained regularly;
5. Proper documentation by ledger keeping of the specimens added and used /discarded/ taken is mandatory.

5.7 Safe storage of reagents and other chemicals

The following general suggestions for safe storage of chemicals in the laboratory should be implemented

1. The quantities of chemicals that are stored within a laboratory should be minimized. Bulk quantities of chemicals (i.e., larger than 4 litres) must be stored in a separate storage area;

    a. Transfer of flammable liquid from 16 litres or larger metal containers may NOT be done in the laboratory.

2. Chemicals must be stored at an appropriate temperature and humidity level.

    a. As a rule, chemicals should NOT be stored near heat sources, such as steam pipes or laboratory ovens;

    b. Chemicals should NEVER be stored in direct sunlight.

3. Chemicals should be dated when received and when opened.

    a. If the chemical is one that degrades in quality or becomes unsafe after prolonged storage, the shelf-life expiration date should also be displayed.

4. Visual inspection of the material and its container should be conducted routinely.

    a. Chemicals should NOT be routinely stored on the bench tops, where they are unprotected from exposure and participation in a fire situation and are also more readily knocked over;

    b. Each chemical should have a specific storage area and be returned there after use;

    ` c. Large quantities of flammable materials should NOT be stored in the laboratory.

    i. Only the amounts needed should be kept on bench tops, the remainder should be kept in flammable storage cabinets.

5. Laboratory shelves should have a raised lip along the outer edge to prevent containers from falling.

    a. NEVER allow the container to hang off the edge of the shelf;

    b. Liquid or corrosive chemicals should NEVER be stored on shelves above eye-level;

    c. Glass containers should not touch each other on the shelves;

6. Adequate security must be provided so that unauthorized personnel do NOT have access to hazardous materials.

7. Chemicals must NEVER be stored on the floor, NOT even temporarily;

8. Flammable materials must NEVER be stored in domestic-type refrigerators.

    a. Only explosion-proof or flammable material refrigerators should be used for storage of these chemicals within a laboratory environment

Chapter 6: SAFETY DURING BIOLOGICAL SPECIMEN TRANSPORTATION

6.1 Introduction

Transport of infectious and potentially infectious materials is subject to strict national and international regulations. These regulations describe the proper use of packaging materials as well as other shipping requirements. Shipment of infectious substances must be made according to applicable transport regulations.

6.2 Specimen transport within the facility

- The laboratory personnel / transporter should use appropriate PPE during transport of specimens within the facility;
- A secondary leak-proof container should be used to avoid/ secure accidental leakage or spillage from the primary container and the specimen containers should always be kept upright and labelled;
- The secondary containers may be of metal or plastic, should be autoclavable or resistant to the action of chemical disinfectants;
    - Secondary container should be regularly decontaminated;
    - Absorbent material should be placed between primary and secondary containers.
- Basket or trolley should be used for the transportation of the clinical specimens within the facility.

6.3 Specimen transport within the country

- The person involved in specimen packaging should use appropriate PPE;
- Hands must be washed before and after the packaging procedure;
- The basic triple packaging system (Figure 6.1 and 6.2) shall be followed for transport of specimens within the country from one facility to another;
- Volume and/or weight limits for packaged infectious substances are to be followed strictly;
- Specimen data forms, letters and other types of information that identify or describe the specimen and identify the shipper and receiver, and any other documentation required must also be provided according to regulations;
- Triple layer packaging system applies for transportation of biological specimens within the country following relevant SOP.

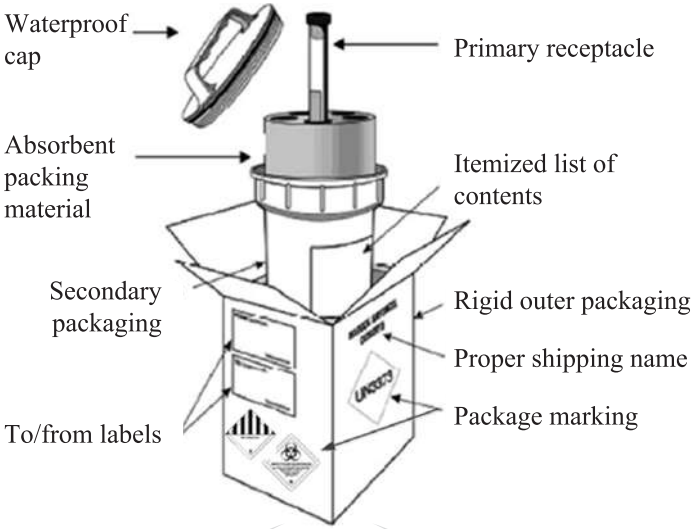


Figure 6.1 Triple package for transport of infectious specimen

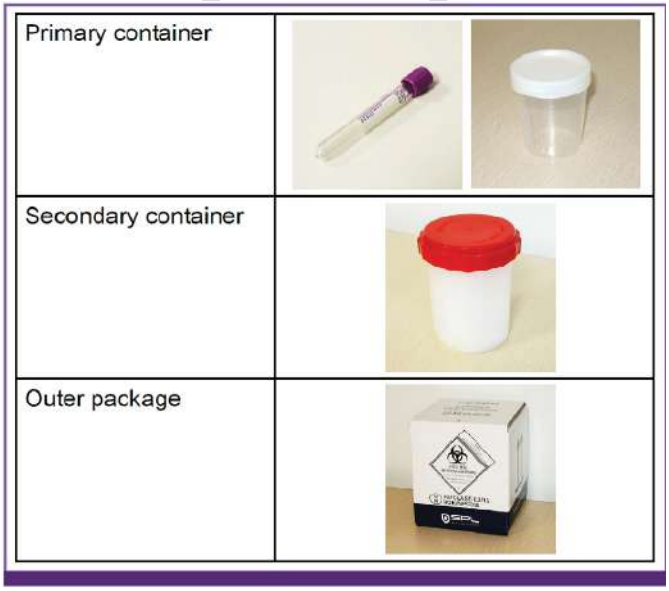


Figure 6.2 Materials required for Triple packaging system

6.4 International transport regulations

- The basic triple packaging system applies for the transport of a variety of infectious substances. However, high-risk organisms must be shipped according to more stringent requirements;

  a. For further details about the use of the different packaging according to the materials to be transported, it is advisable to follow guidelines for transportation of biological specimens.

- Related transport authority should have facilities and permission to transport biological specimens.

Chapter 7: LABORATORY EMERGENCY AND SPILL MANAGEMENT

7.1 Introduction

Each laboratory should have an emergency and spill management system to minimize the incidence and risk of exposure during any emergency or spillage. All laboratory personnel have the responsibility to fully understand the safety guidelines regarding laboratory emergency and spill management. The laboratory head/ Institutional Bio-safety Officer (IBO) has the responsibility to make sure that all laboratory personnel must complete necessary training for management of any emergency or spill in the laboratory.

7.2 Preparedness for an emergency

- Keep an adequately equipped emergency response supplies, i.e., First Aid Kit (Appendix 2), Spill Kit (Appendix 3), and Antidote, including Safety Shower (Figure 3.9) /Eyewash (Figure 3.8 and 3.8) and fire extinguisher (Appendix 4) in common place of the laboratory that is known and easily accessible to all staffs related to laboratory works.
- Fire extinguisher should be within expiry date;
- A phone directory with phone numbers for emergency situation should be maintained;
- The building's floor plan and emergency exit routes should be known to every laboratory personnel;
- **Staff should be trained on**
    - Use of first aid kit, antidote and spill kit;
    - Use of safety shower and eyewash;
    - Use of fire extinguisher;
    - Management of spills;
    - Safe emergency exit;
    - Medical emergencies;
    - Fire drill should be conducted annually;

7.3 Spill Management

- A spill kit should be available to manage any type of spill such as dry spill, liquid spill, chemical spill, and spillage in a closed area;
- Any spill should be informed to laboratory head and recorded accordingly;
- Spill should be managed by adequately trained and authorized person only;
- SOP should be strictly followed for spill management.

7.4 Incident specific emergency management

7.4.1 Accidental needle stick injury

- Any accidental needle stick injury should be informed to laboratory head;
- Do not apply pressure over the injury;
- Wash injury site with soap and water before performing other necessary measure(s);
- The laboratory should have a referral system to manage accidental needle stick injury.

7.4.2 Accidental inhalation and ingestion

- Any accidental inhalation and ingestion should be informed to laboratory head;
- The laboratory should have a referral system to manage accidental inhalation and ingestion;
- Seek medical help immediately.

7.4.3 Fire explosion

- Remain calm and activate the fire alarm or inform the emergency service department (fire services 999);
- Use fire extinguisher;
- Report to your assembly point/ area and the safest route available;
- Assist others without endangering your safety;
- Walk, do not run;
- Evacuate the building;
    - Do not waste time turning off equipment, collecting papers, or gathering personal property;
    - Feel the doors to chack if they are hot before opening them;
    - If there is smoke, crawl low because the air is fresher and cooler over the floor.
- Use stairs, do not use elevators;
- Do not enter the building after evacuation without fire department's approval.

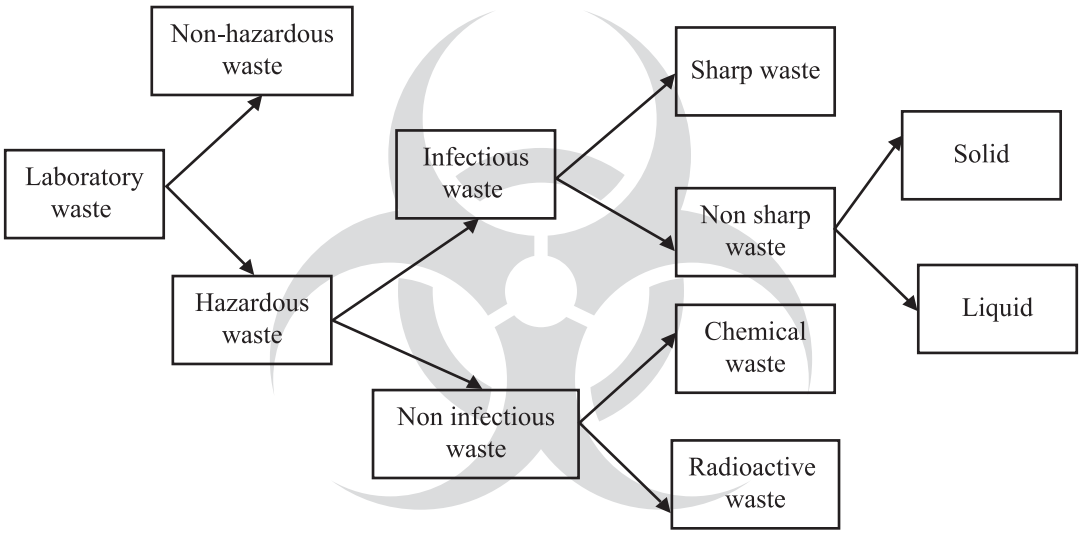
Note: Any laboratory emergency and spillover incidences must be recorded in an incidental record registry.

Chapter 8: BIOMEDICAL LABORATORY WASTE MANAGEMENT

8.1 Introduction

Laboratory waste is a potential reservoir of pathogenic microorganisms and requires appropriate management. Numerous diseases can be transmitted in the community as well as to those who handle wastes generated at laboratories. A biomedical laboratory should always have a proper waste management system in place. The authority should ensure that the persons involved in waste management are following laboratory waste management protocol/standard operating procedure (SOP) in accordance with the existing laws of the country.

Biomedical laboratories generate waste ranging from non hazardous general waste to hazardous infections, radioactive and chemical wastes. The wastes generated at the biomedical laboratories are classified as in the following flow-chart;



Hazardous waste poses a substantial threat to human health or the environment as it may contain infectious agents, hazardous chemicals, radioactive materials and sharps. So, this waste is needed to be dispose of properly for the sake of environment and human health.

Considering the biosafety and biosecurity issues linked with biological wastes, government of Bangladesh developed and endorsed 'চিকিৎসা বর্জ্য (ব্যবস্থাপনা ও প্রক্রিয়াজাতকরণ) বিধিমালা, 2008, and 'বাংলাদেশ পরিবেশ সংরক্ষণ আইন, ১৯৯৫ (১৯৯৫ সনের ১নং আইন)' for appropriate management of biological waste.

8.2 Five guiding principles of biomedical waste management

- The 'polluter pays principle' implies that all producers of waste are legally and financially responsible for safe and environmentally sound disposal of the waste they produce.

- The 'precautionary principle' is persuative governing health and safety protection. It was defined and adopted under Rio Declaration on Environment and Development (UNEP, 1972) as principle 15: 'Where there are threats of serious or irreversible damage to the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.

- The 'duty of care principle' recommends that treatment and disposal of hazardous substances or wastes or related equipment is ethically responsible for using the utmost care in that task. This principle is best achieved when all parties involved in the production, storage, transport, treatment and final disposal of hazardous wastes (including health-care waste) are appropriately registered or licensed to produce, receive and handle named categories of waste.

- The 'proximity principle' recommends that treatment and disposal of hazardous waste take place at the closest possible location to its source to minimize the risks involved in its transport. Similarly, every community should be encouraged to recycle or dispose of the waste it produces, inside its own territorial limits, unless it is unsafe to do so.

- The 'prior informed consent principle' as embodied in various international treaties is designed to protect public health and the environment from hazardous waste. It requires that affected communities and other stakeholders be apprised of the hazards and risks, and that their consent be obtained. In the context of health-care waste, the principle could apply to the transport of waste and the sitting and operation of waste-treatment and disposal facilities.

8.3 Key activities of waste management

- The authorities should ensure that SOPs are followed for laboratory waste management;

- **Waste minimization:** Minimize waste through the "3R" principles i.e. waste reduction, reuse and recycling.

- **Waste segregation:** It is the responsibility of the laboratory personnel who generates wastes to segregate at the site of generation to the specific colour coded bin.

- Usage of colour-codes for different types of wastes is different across the world. However, for Bangladesh, the following are the recommended colour codes for waste segregation:

Black bin: Non hazardous general waste such as wrapping, packaging and printing materials, stationery items.

Red bin: Used and unused sharp waste such as needles (with or without syringe), blood slides, cover slips, lancet, broken glass.

Blue bin: Liquid waste such as blood, body fluid, expired/ contaminated reagent, waste generated from laboratory activity (viz.washing, cleaning and disinfecting), microbiological liquid culture material, waste generated from analyzer.

Yellow bin: Infectious, pathological and anatomical wastes, such as cotton swab, dressing, swab stick, gloves, test tubes, sample cup, micropipette tips, petri dish, microbiological solid culture media, histopathological specimens.

Silver bin: Radioactive waste (e.g. radioactive diagnostic materials).

Green bin: Non contaminated recyclable plastic such as disposable bottle, unused sample cup and tips.

- **Waste transportation:** Waste should be transported in closed container(s) to the site of treatment and disposal with appropriate label on the bin/bags for Waste treatment and disposal:
    - Liquid waste from blue bin should be disposed of in drain, after proper chemical treatment;
    - Infectious disposal solid wastes (viz., contaminated swab) from yellow bin should be treated by autoclaving prior to be buried. Infectious solid waste (viz., test tube, tip, sample cup) can be reused after chemical treatment;
    - Sharp waste from red bin should be dicontaminated by using effective chemical disinfection methods or by autoclaving, prior to final disposal by incineration or landfill;
    - Non-hazardous wastes from black bin should be disposed of into the bin provided by City Corporation (CC) without any treatment;
    - Non-contaminated plastic from the green bin is recycled after chemical treatment.
- Waste contaminated with radioactive diagnostic material should not be autoclaved, rather contact with Atomic Energy Commission or appropriate authority for proper disposal. Records of laboratory waste management should be maintained and updated.

Figure: 8.1 Colour Coded Bins

Chapter 9: BIOSECURITY

9.1 Introduction

Laboratory biosecurity refers to institutional and personal security measures designed to prevent the loss, theft, misuse, sabotage, diversion or intentional release of pathogens and toxins.

9.2 Objective of biosecurity

To prevent loss, theft, sabotage or misuse of microorganisms, biological materials, and research-related information.

9.3 Elements of a biosecurity program

Biosecurity program components should be site-specific and based upon organizational threat/vulnerability assessment and as determined appropriate by facility management. Elements discussed below should be implemented, as needed, based upon the risk assessment process. They should not be taken as "minimum requirements" or "minimum standards" for a biosecurity program.

9.4 Program management

If a biosecurity plan is implemented, institutional management must support the biosecurity program. Appropriate authority must be delegated for implementation and the necessary resources provided to assure program goals are being met. The biosecurity program should be integrated into relevant institutional policies and plans.

9.5 Physical security-access control and monitoring

Biosecurity program are intended to prevent the removal of assets for non-official purposes. An evaluation of the physical security measures should include a thorough review of the building and premises, the laboratories, and biological material storage areas. Access should be limited to authorized and designated employees, based on the need to enter sensitive areas. Methods for limiting access could be as simple as locking doors or having a card key system in place. The need for entry by visitors, laboratory workers, management officials, students, cleaning/maintenance staff, and emergency response personnel should be considered.

9.6 Personnel management

Personnel management includes identifying the roles and responsibilities of employees who handle, use, store and transport dangerous pathogens and/or other important assets. Policies should be developed for laboratory personnel and visitor identification, visitor management, access procedures, and reporting of security incidents.

9.7 Inventory and accountability

Material accountability procedures should be established to track the inventory, storage, use, transfer and destruction of dangerous biological materials and assets when no longer needed. The objective is to know what agents exist at the facility, where they are located, and who is responsible for them. To achieve this, management should define: (i) the materials (or forms of materials) subject to accountability measures; (ii) records to be maintained, update intervals and timelines for record maintenance; (iii) operating procedures associated with inventory maintenance (e.g., how material is identified, where it can be used and stored); and (iv) documentation and reporting requirements.

It is important to emphasize that microbiological agents are capable of replication and under suitable condition are often expanded to accommodate the nature of the work involving their use. Therefore, knowing the exact "working" quantity of organisms at any given time may be impractical. Depending on the risks associated with a pathogen or toxin, management can designate an individual who is accountable, knowledgeable about the materials in use, and responsible for security of the materials under his or her control.

9.8 Information security

Policies should be established for handling sensitive information associated with the biosecurity program. For the purpose of these policies, "sensitive information" is that which is related to the security of pathogens and toxins, or other critical infrastructure information. Examples of sensitive information may include facility security plans, access control codes, agent inventories and storage locations. The objective of an information security program is to protect information from unauthorized release and ensure that the appropriate level of confidentiality is preserved. Facilities should develop policies that govern the identification, marking and handling of sensitive information. Policies for properly identifying and securing sensitive information including electronic files and removable electronic media (e.g., CDs, computer drives) should be developed.

9.9 Transport of biological agents

Material transport policies should include accountability measures for the movement of materials within the facilities (e.g., between laboratories, during shipping and receiving activities) and outside of the facility (e.g., between institutions or locations). Transport policies should address the need for appropriate documentation and material accountability and control procedures for pathogens in transit between locations. Transport security measures should be instituted to ensure that appropriate authorizations have been received and that adequate communication between facilities has occurred before, during, and after transport of pathogens or other potentially hazardous biological materials. Personnel should be adequately trained and familiar with regulatory and institutional procedures for proper containment, packaging, labeling, documentation and transport of biological materials.

9.10 Accident, injury and incident response plans

Laboratory security policies should consider situations that may require emergency responders or public safety personnel to enter the facility in response to an accident, injury or other safety issue or security threat. The preservation of human life, the safety and health of laboratory employees and the surrounding community must take precedence in an emergency over biosecurity concerns. Facilities are encouraged to coordinate with medical, fire, police and other emergency officials when preparing emergency and security breach response.

9.11 Reporting and communication

Communication is an important aspect of a biosecurity program. A "chain-of-notification" should be established in advance of an actual event. This communication chain should include laboratory and program officials, institution management, and any relevant regulatory or public authorities. The roles and responsibilities of all involved officials and programs should be clearly defined. Policies should address the reporting and investigation of potential security breaches (e.g., missing biological agents, unusual or threatening phone calls, unauthorized personnel in restricted areas).

9.12 Training and practice drills / rehearsal

Biosecurity training is essential for the successful implementation of a biosecurity program. Training programs that inform and educate individuals regarding their responsibilities within the laboratory and the institution. Practice drills should address a variety of scenarios such as loss or theft of materials, emergency response to accidents and injuries, incident reporting and identification of and response to security breaches. These scenarios may be incorporated into existing emergency response drills such as fire drills or building evacuation drills associated with bomb threats. Incorporating biosecurity measures into existing procedures and response plans often provides efficient use of resources, saves time and can minimize confusion during emergencies.

9.13 Security updates and re-evaluations:

The biosecurity risk assessment and program should be reviewed and updated routinely and following any biosecurity-related incident. Re-evaluation is a necessary and on-going process in the dynamic environments of today's biomedical and research laboratories. Biosecurity program managers should develop and conduct biosecurity program audits and implement corrective actions as needed. Audit results and corrective actions should be documented. The appropriate program officials should maintain records.

9.14 Select microbial pathogens:

If an entity possesses, uses or transfers following microbial pathogen agents, it must comply with all requirements of the National Program.

9.14.1 Bacterial

- Bacillus anthracis;
- Yersinia pestis;
- Clostridium botulinum;
- Clostridium perfringens;
- Vibrio cholerae;
- Francisella tularensis.

9.14.2 Viral

- Ebola virus;
- Small pox virus;
- Avian influenza virus.
- SARS CoV2

9.14.3 Fungal

9.14.4 Parasite

9.14.5 Prion

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চিকিৎসা-বর্জ্য (ব্যবস্থাপনা ও প্রক্রিয়াজাতকরণ) বিধিমালা, ২০০৮

বাংলাদেশ পরিবেশ সংরক্ষণ আইন, ১৯৯৫ (১৯৯৫ সনের ১নং আইন)

Glossary

Biohazardous waste

Any waste containing infectious material or potentially infectious substances such as blood and body fluids, sharp wastes such as needles, blades, glass pipettes, and other wastes that can cause injury during handling are of special concern.

Biological specimens

Biological specimens for laboratories considered under this guideline include specimens collected from humans only including blood, body fluids, etc.

Biological substance

Biological substance include any material that contain or is reasonably expected to contain a microorganism(s) (such as bacteria, viruses, rickettsiae, parasites, or fungi) or other agents that can cause disease in humans or animals.

Biomedical waste

It is the waste generated from handling biological specimens in a medical laboratory. All biomedical specimens are considered as potentially infectious and should be treated as infectious wastes.

Biosafety

Laboratory bio-safety is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

Biosecurity

It describes the protection, control and accountability for valuable biological materials (VBM). It refers to institutional and personal measures designed to prevent loss, theft, sabotage, misuse, diversion or intentional release of pathogen or toxin.

Good clinical laboratory practice

Good clinical laboratory practice (GCLP) is a set of standards that provide guidance on implementing Good Laboratory Practice (GLP) principles for the analysis of, specimens for diagnostic and research purposes.

Medical laboratory

Laboratories working with human biological specimens and for the purpose of this guideline, medical laboratory includes clinical and diagnostic laboratories, biomedical research laboratories and public health laboratories.

Standard PPE

A set of personal protective equipment (PPE) recommended for standard precautions. This set consists of gloves, laboratory coat, mask, face shield, head cover/cap, goggles, shoe covers/ front covered shoes.

Appendices

Appendix 1
List of microorganisms according to risk group

Sl No.	Risk group	Microorganisms included			
		Bacteria	**Viruses**	**Parasites**	**Fungi**
1	**Risk group 1**	1. Micrococcus spp. 2. Lactobacillus spp. 3. *Bacillus subtilis*			Common moulds and yeasts
2	**Risk group 2**	1. Actinobacillus 2. Actinomyces spp. 3. *Bacillus cereus* 4. Bacteroides 5. *Bordetella pertussis* 6. Brucella spp. 7. *Campylobacter jejuni* 8. Clostridium spp. 9. *Corynebacterium diptheriae* 10. Diphtheroids 11. Enterobacter 12. *Escherichia coli* 13. *Haemophilus ducreyi* 14. *Helicobacter pylori* 15. *Klebsiella spp.* 16. *Legionella pneumophila* 17. *Leptospira interrogans* 18. *Listeria monocytogenes* 19. Moraxella spp. 20. Mycobacterium spp. - excluding members of the *Mycobacterium tuberculosis* complex *(M. tuberculosis, M. bovis, M. africanum, M. pinnipedii, M. microti, M. caprae, "M. canettii")* 21. Neisseria spp. 22. Pseudomonas spp. 23. *Salmonella enterica spp.* 24. Shigella spp. 25. *Staphylococcus aureus* 26. *Streptococcus pneumoniae* 27. *Vibrio cholerae,* serogroup O1, serogroup O139 (Bengal) 28. *Mycoplasma pneumoniae*	1. Adenovirus types 1, 2, 3, 4, 5 and 7 2. Coxsackievirus 3. CMV 4. Dengue virus 5. Echovirus 6. EBV 7. Hepatitis A virus (HAV) 8. Hepatitis B virus (HBV) 9. Hepatitis C virus (HCV) 10. Hepatitis D Virus 11. Hepatitis E virus 12. Herpes simplex virus 13. Human Coronavirus (excluding SARS-Co-V) 14. Human papillomavirus 15. Human Parainfluenza virus 16. Human rotavirus 17. Influenza virus type A (excluding 1918 influenza A (H1N1) strain and subtypes H5, H7 and H9) 18. Influenza virus (B and C) 19. Measles virus 20. Norwalk virus 21. Parvovirus B19 22. Respiratory syncytial virus 23. Rhinovirus 24. Rubella virus 25. Vaccinia Virus 26. Varicella-zoster virus	1. Toxoplas ma gondii 2. Leishman ia spp	1. Candida albicans 2. Cryptococcu s neoformans

3	**Risk group 3**	1. *Chlamydophilia psittaci* 2. *Rickettsia rickettsii* 3. *Mycobacterium tuberculosiscomplex (including M. tuberculosis, M. bovis, M. africanum, M. pinnipedii, M. microti, M. capraeand M. canettii)* 4. *Bacillus anthracis*	1. Chikungunya virus 2. Crimean- Congo haemorrhagic fever virus 3. Eastern equine encephalitis virus (EEEV) 4. Western equine encephalitis virus (WEEV) 5. Hantavirus spp. 6. Human immunodeficiency virus (HIV) 7. Human T-lymphotropic virus (HTLV) 8. Influenza A virus subtypes H5, H7 and H9. 9. Yellow fever virus, 10. West Nile virus (WNV) 11. Vesicular stomatitis virus (VSV) 12. Severe acute respiratory syndrome (SARS) associated coronavirus 13. Rabies virus		1. Histoplasma capsulatum
4	**Risk group 4**		1. Ebola virus 2. Japanese encephalitis virus 3. Lassa virus 4. Marburg virus 5. Variola virus 6. Nipah virus 7.SARS CoV2		

Appendix 2
Components of first aid kit:

1. Sterile dressing to cover wounds;
2. Absorbent cotton wool;
3. Triangular and roll bandage;
4. Band aid;
5. Sterile eye pad;
6. Roll of adhesive tape;
7. Alcohol pad;
8. Safety pins;
9. Scissors;
10. Sodium bicarbonate powder;
11. Boric acid powder;
12. Pain killer;
13. Proton pump inhibitor / H2 blocker;
14. Antacid;
15. Antiseptic lotion/cream;
16. Silcream (silver sulfadiazine);
17. Thermometer;
18. Blood pressure machine.

Figure 11. 1 First aid kit

Appendix 3
Components of laboratory spill kit

1. Disposable powder free gloves (nitrile / rubber / vinyl) - a few pairs;
2. Caution Chemical Hazard banners tape, 6' rolls - 2 pc;
3. Plastic bags (For disposal) – 6 pc;
4. Hazardous Waste Tags - 1 pad;
5. Ball point pen - 1 pc;
6. Lab Marker Pen - 1 pc;
7. Container of Sodium Bicarbonate, marked "Acid Neutralizer - Sodium Bicarbonate" - 1 pc;
8. Container of Citric Acid, marked "Base Neutralizer - Citric Acid" - 1 pc;
9. Mercury Sponge containers - 1 pc;
10. Mercury In-Line Vacuum Trap Kit (bagged with tubing and disposal bags) - 1 pc;
11. pH paper - 2 vials;
12. Dust Pan - 1 pc;
13. Foxtail Brush - 1 pc;
14. Personal Protective Equipment;
15. Laboratory tongs — to pick up broken glass;
16. Absorbent pillows/towels (2/bag);
17. Thermometer;
18. Blood pressure machine.

Figure 11. 2 Spill kit

Figure 11.3 “Caution” Chemical Hazard banners tape

Appendix 4
Use of fire extinguisher

Appendix 5
List of laboratory activities that can generate infectious aerosols

1. Pouring off supernatant fluids, particularly from a considerable height into a container.
2. Vigorous tapping of a tube to re-suspend sediment.
3. Opening cultures and the rapid snap-closing of specimen or culture containers.
4. Heating a contaminated wire loop in an open Bunsen burner flame.
5. Using a long springy loop which is not properly closed.
6. Rapid rinsing of Pasteur pipettes or plastic bulb pipettes, particularly when a discard container is almost full.
7. Vigorous shaking of unstoppered tubes in a rack.
8. Centrifuging specimens or infected fluids in open buckets, particularly when using a hand operated centrifuge or an angled head centrifuge and the tubes are more than three-quarters full.
9. Opening a centrifuge immediately following the breakage of a tube or container of infected fluid before the aerosols have had time to settle.
10. Dropping or spilling a specimen or culture.
11. Mouth-pipetting and expelling an infected fluid, particularly blowing out the last drop.

Appendix 6
Biosafety and biosecurity assessment tool

6.1 Basic Laboratory - Biosafety Level 1

	6.1.1. Laboratory	**YES**	**No**	**N/A**
a	Limited access			
b	Proper signage: e.g. biohazard, ultraviolet light etc.			
c	Relevant SOP for work activities available and followed			
d	Laboratory equipment properly labeled (biohazardous, radioactive, toxic)			
	6.1.2. Laboratory design			
a	Facility designed for easy cleaning			
b	Corridors and exits are free from obstructions			
c	All storage shelves secured			
d	Bench tops waterproof and resistant to acids, alkali, organic solvents, heats chemicals used to decontaminate the work surface			
e	Adequate illumination/ lighting provided			
f	Adequate storage space available and appropriately used			
g	Adequate ventilation			
h	Windows fitted with insect -proof screen (when windows can be opened)			

	6.1.3 Gas cylinders			
a	All cylinders secured			
b	Caps on reserve cylinders			
c	Asphyxiating and hazardous gases only in designated ventilated rooms			
d	No excess or empty cylinders present in non-designated areas			

	6.1.4 Chemicals			
a	Flammables stored in storage cabinet for flammables			
b	Chemicals segregated properly based on intrinsic properties when stored			
c	Hazardous chemicals stored safely and securely			
d	Working stock chemicals available and easily accessible			
e	MSDS/ CSDS is available and easily accessible for all chemicals			

	6.1.5 Refrigerators/ freezers/ cold rooms			
a	No food for human consumption stored			
b	Flammables placed in explosion- proof/safe units			
c	All material containing carcinogens, radioactivity and/ or biohazards are labelled externally			
d	Cold room has emergency release			
e	Cold room has audible alarm or temperature monitoring system			

	6.1.6 Electrical equipment			
a	No overloaded extension cords or electrical strips			
b	Earths/ grounds present on electrical outlets and cords			
c	No electrical connections in wet areas e.g. sinks, under showers, etc			
d	All equipment and wiring in good working condition			
e	Power strips mounted off the floor			
f	Proper fuses in conduits			

	6.1.7 Personal protective equipment			
a	Eyewash available in laboratory			
b	Safety shower available			
c	Personal protective equipment available (gloves, gowns, goggles, etc)			
d	Occupants properly attired			
e	Laboratory coats, gowns, smocks, gloves and other personal protective clothing not worn outside the laboratory			
f	Personal protective equipment available for cryogenic storage			

	6.1.8 Waste management			
a	Wastes segregation implemented			
b	Chemical waste containers tagged, labelled, dated and			
	kept closed/ stored			
c	Biohazardous waste containers appropriately handled			
	and disposed			
e	All sharps (needles, broken glass, scalpel blades) are disposed in sharps bin or designated durable puncture containers			

	6.1.9 Occupational health and safety program available			
a	Hazard communication (Laboratory personnel advised of all potential hazards)			
b	Respiratory protection			
c	Hearing conservation			
d	Chemical Spill Kit available			
e	Biological Spill Kit available			
f	First aid Kit available			
g	Emergency response plan (ERP) in place			
h	Reporting of incidents, accidents and illness			

	6.1.10 General engineering controls			
a	Sink available for hand washing			
b	No exposed machine parts (pulleys, gears)			
c	Water purification system in good condition			

	6.1.11 General practices and procedures			
a	Food for human consumption stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose			
b	Microwave oven(s) clearly labelled "Strictly for Laboratory Materials Only"			
c	Eating, drinking, smoking and/ or applying of cosmetics not allowed in the laboratory			
d	Pressurized glass containers taped or shielded (i.e., vacuum traps)			
e	Mouth pipetting prohibited			
f	Mechanical pipetting devices available			
g	Protective laboratory clothing stored separately from street clothing			

	6.1.12 General laboratory housekeeping			
a	Bench-top cleaned and not cluttered			
b	Laboratory floor free from trip hazards			
c	Broken glassware handled by mechanical means (brush and dustpan, tongs, etc.)			
d	Chemical inventory system available			
e	Pest control program implemented			

	6.1.13 Fire protection			
a	Sprinkler heads free and unobstructed			
b	No wiring or tubing through door openings			
c	Minimum passage width of 1 meter (m) in laboratory			
d	Minimum combustibles stored in laboratory			
e	Adequate fire extinguisher available			
f	Fire alarm available and drills for evacuation implemented			

6.2 Basic Laboratory - Biosafety Level 2

This form is used in addition to the Biosafety Level 1 laboratory safety checklist

	6.2.1 Biological safety cabinet (BSC)	YES	No	N/A
a	Annually certified by qualified person			
b	BSC surface wiped down with appropriate disinfectant at beginning and end of each procedure			
c	Front grill and exhaust filter unobstructed			
d	No open flames used inside cabinet			
e	Vacuum lines have in-line filters and disinfectant traps in use			
f	Location of BSC not directly opposite entrance and below in flow air vent			
g	BSC used when there is potential for creating infectious aerosols			

	6.2.2 Administrative control			
a	Access limited and restricted to authorized personnel			
b	Appointment of BSO			
c	Laboratory biosafety training program implemented			
d	Proper documentation and records (material inventory, incident reporting, etc)			
e	Immunization plan available			
f	Appropriate medical surveillance available			
g	Biosafety manual prepared and adopted			
h	Staff competency evaluated			

	6.2.3 Laboratory			
a	Biohazard sign posted on laboratory door as appropriate			
b	Information on signage accurate, current and indicate emergency contact numbers			
c	Sign legible and not defaced			
d	All doors closed			
e	All windows sealed or closed permanently			
f	Hand washing sink available near laboratory exit			

	6.2.4 Decontamination			
a	Decontaminant appropriate to the organism(s) in use			
b	All spills and accidents involving infectious materials reported to the laboratory supervisor			
c	Appropriate disinfectant used during spill cleaning			
d	Work surfaces decontaminated before and after each procedure, daily and after spills			
e	Biological spill kit available (content e.g. disinfectant should be periodically checked for expiry)			

	6.2.5 Handling of contaminated waste			
a	Infectious waste segregated and placed in autoclavable bags			
b	Waste containers or bags properly labeled and closed securely			
c	Culture stocks and other infectious waste properly decontaminated by autoclaving or chemical disinfectant before disposal			
d	Infectious waste containers not overfilled			
e	Materials decontaminated outside the laboratory transported in closed, durable, leak proof containers			
f	Co-mingled waste (biological waste mixed with chemical or radiological waste) / decontaminated prior to disposal according to local regulations			

	6.2.6 Personal protection			
a	Gloves worn when handling infectious material or contaminated equipment			
b	Face protection provided when working outside the biosafety cabinet with infectious material			

6.2 Basic Laboratory - Biosafety Level 2

This form is used in addition to the Biosafety Level 1 and Biosafety Level 2 laboratory safety checklist

	6.3.1 Facility	YES	No	N/A
a	Laboratory separated from unrestricted traffic flow in building			
b	Access to laboratory through an anteroom with self- closing doors			
c	All penetrations in laboratory sealed or sealable foe decontamination			
d	Room exhaust air single-pass and exhausted away from occupied areas			
e	Controlled ventilation system to monitor directional airflow available			
f	Air recirculated into the containment laboratory must be HEPA filtered			
g	Audible or clearly visible alarms for engineering controls available with a proper back up plan			
h	A dedicated autoclave is available and certified annually			
i	Vacuum line has filters and traps			
j	Backflow prevention to water supply			
k	Surfaces of floor, walls and ceilings should be easily cleaned			

	6.3. 2 Administrative control			
a	Controlled access to authorized and trained personnel (e.g. Card key access or CCTV)			
b	Competency training program available on BSL3 practices			
c	Appropriate and adequate personal protective equipment available			
d	Medical surveillance program implemented			
e	Appropriate material inventory system available			
f	All infectious agents and materials secured (e.g. freezers are lockable)			

Appendix 7
Laboratory biological risk assessment worksheet

Name of the institute/Hospital…….....…..

Name of the Laboratory…….....……..

Name of the Laboratory Head…….....……

Usually a laboratory performs different procedures with different microbiological agents. Each procedure in the laboratory needs an agent-specific Biological Risk Assessment.

Section I: Complete All Data Entry in this section

1. **Agent Used:**
2. **Risk Group of Agent (check chapter-1): 1 2 3 4**
3. **Is a vaccine available? Yes No**
4. **Laboratory procedure used: Microscopy Culture Serology Molecular**
5. **For Risk Group 2-3, is there a splash potential? Yes No**
6. **For Risk Group 2-3, does the procedure generate aerosol or large concentration**

(e.g., cell culture, vortex, centrifuge, aerosol chamber, sonicate) **Yes No**

Section II: Data will be calculated in this section according to the answers entered above in Section I

1. **Facility and work practices of biological safety levels (BSLs)**

   Facility BSL 1 2 3 4

   Work Practices BSL 1 2 3 4

2. **Biological Safety Cabinet Class I Class II Class III**
3. **Personal Protective Equipment Needed for Procedure and available:**

   a. **Gloves (latex/nitrile) Yes No**

   b. **Eye protector** (safety glasses/ goggles + face shield): **Yes No**

   c. **Laboratory coat** (white/blue smock/coveralls): **Yes No**

   d. **Respirator** (surgical mask/N-95 Mask): **Yes No**

4. **Medical Protection and Surveillance**

   a. **Medical Monitoring required: Yes No**

   b. **Vaccine recommended: Yes No**

   c. **Respiratory Protection Program: Yes No**

Please Identify risk and recommend risk management accordingly

Activities or Specific Tasks	Hazards	Current Controls : Engineering, Administrative, and PPE	Gaps	Consequences	Estimated risk	Additional Controls /Process Improvements Needed to Reduce Risk to the Lowest Possible Level

Comments

Signature of biosafety officer

Appendix 8

Terms of references (ToR) of biosafety and biosecurity coordination committee (BBCC)

8.1 Terms of references

8.1.1 Chairperson

- Overall supervision of BSBS activities of the labroratoryes in health sectors;
- Preside over all BSBS coordination meetings;

8.1.2 Member Secratory

- Responsible to ensure all BSBS related activities in respective laboratories through regular monitoring & constant supervisions in close contacts with the Institutional Biosafety Officer (IBO);
- Organize time to time training of laboratory personnel on biosafety and biosecurity;
- Initiate assessment of different laboratories;
- Monitor and evaluate the BSBS programs of institutional Biosafety and Biosecurity committees;
- Give recommendations on the basis of assessment, monitoring and evaluation for the improvement of BSBS program
- Update BSBS guideline;
- Update BSBS SOPs.
- Update BSBS training modules:

Terms of references (ToR) of Biosafety and Biosecurity Core Committees (BSCC)

8.2 Terms of references

8.2.1 Chairperson

- Advise for ensuring Biosafety and Biosecurity of the laboratory;
- Call for and preside over meetings.

8.2.2 Coordinator (Institutional Biosafety Officer, IBO)

- The role of IBO in a respective institution/ hospital remains the principal responsibility of looking after and verifying every step of BSBS activities. S/he must attend/address all plans/missing steps, safety breach/accidental events, etc
- Must forward a written incident report to BSBS Coordination Committee (BBCC) (addressing Chairman) or his/her representative along with verbal information over telephone as advance urgent communication
- In absence of an IBO, the IBC Chairman may select the IBO based on rational judgment of having skill/expertise in disease prevention and control, epidemiology, and infection control/ waste management and environmental hazards;
- In absence of the chairperson, the Coordinator will call the meetings;
- However, the IBO will inform/discuss on any untoward issue/ unwanted events on safety breach with the Chairman in prior or, immediately after the event occurred.
- The IBO should inform any incident/accident that may occur in respective institution/ hospital to take immediate action and report it instantly to the Chairman of BBCC;
- The IBO must be aware of such safety breach/ accidents that may occur in the following ways:
    - Any accidental dropping/shedding of blood/body fluid anywhere inside institution/ hospital (floor, table, seats, etc.);
    - Accidental spillage of blood/body fluid/urine/stool/pus/sputum/cough anywhere in lab/waiting room, etc.;
    - Accidental drop/spillage of live/killed microorganism, non/toxic media/reagents anywhere in the lab, etc.
- The IBO should also take care of issues on human ethics including environmental issues during any on-going clinical, laboratory experiments;
- The IBO should also list out any hospital/ laboratory/ project office, who use animal/ human blood/ products or any biological substances or live microorganisms to be more attentive in such cases to record and report duly;
- Thus, the IBO must keep the records all sorts of reports/documents related to BSS issues. Moreover, any occurrences pertaining to mishandling, misplacing or misreporting of test report/ outbreak-investigation/ epidemic report etc. should be noted immediately and reported officially;

- Particularly, any case of incidental, anecdotal & accidental misusage/ miscarriage, spillage/ dropping of any microorganisms killed or live should essentially be investigated, recorded and reported officially;

- All types of theft, loss or missing of any microorganism in any of its forms (seedling, stock-culture/ plates/ broth, ice dried, etc.) should be subjected to analysis and thorough investigation so that all such events be carefully recorded and officially reported instantly;

  a. This is a mandatory WHO-recommended precautionary rules regarding live pathogens and /or substances to safeguard clinical laboratories, research cells from impending loss or environmental threat;

8.2.3 Members

- Attend all meetings of the IBSC and contribute accordingly;

- Support IBO as and when required;

- Carry out any specific assignment made by the IBC for ensuring BSBS.

Terms of references (ToR) of Institutional Biosafety and Biosecurity Committees (IBC) at different levels of medical laboratories

8.3 Terms of references

8.3.1 Chairperson

- Overall supervision of BSBS activities in laboratoryes in health sectors;

- Preside over all BSBS coordination meetings;

8.3.2 Coordinator (Institutional Biosafety Officer, IBO)

- The IBO position should be from the laboratory medicine;

- In absence of an independent IBO, the **IBC Chairman** may select the **IBO** based on rational judgment of having skill/expertise in disease prevention and control, epidemiology, and infection control/ waste management and environmental hazards;

- In absence of the chairman, the coordinator will call the meetings.

- The role of IBO in a respective institution/ hospital remains the principal responsibility of looking after and verifying every step of **BSBS** activities. S/he must attend/address all plans/missing steps, safety breech/ accidental events, etc.;

- However, the **IBO** will inform/ discuss on any untoward issue/ unwanted events on safety breech with the **Chairperson** in prior or, immediately after the event occurred;

    - The **IBO** should inform any incident/ accident that may occur in any institution/ hospital to take immediate action and report it instantly to the Chairperson of **BSCC;**

    - The **IBO must be aware of such safety breech/ accidents** that may occur in the following ways:

        - o Any accidental dropping/ shedding of blood/body fluid anywhere inside institution/ hospital (floor, table, seats, etc.);

        - o Accidental spillage of blood/ body fluid/ urine/ stool/ pus/ sputum/ cough anywhere in laboratory/ waiting room, etc; o Accidental drop/ spillage of live/ killed microorganism, non/ toxic media/ reagents anywhere in the lab, etc.

    - The **IBO should** also take care of issues on human ethics including environmental issues during any on-going clinical, laboratory experiments;

    - The **IBO** should also list out any hospital/ laboratory/ project office, who use animal/ human blood/ products or any biological substances or live microorganisms to be more vigilant in such cases to record and report duly;

    - Thus, the **IBO** must keep the records all sorts of reports/documents related to BSS issues. Moreover, any occurrences pertaining to mishandling, misplacing or misreporting of test report/ outbreakinvestigation/ epidemic report etc. should be noted immediately and reported officially.

    - Particularly, any case of **incidental, anecdotal and accidental** misusage/ miscarriage, spillage/ dropping of any microorganisms killed or live should essentially be investigated, recorded and reported officially;

    - All types of theft, loss or missing of any microorganism in any of its forms (seedling, stock-culture/ plates/ broth, ice dried, etc.) should be subjected to analysis and thorough investigation so that all such events be carefully recorded and officially reported instantly;

        a. This is a mandatory WHO-recommended precautionary rules regarding live pathogens and/or substances to safeguard clinical laboratory, research cell or mil-genetics center from impending loss or environmental threat;

        b. Moreover, this in turn would comply with the rules of **Cartagena protocol**- where **Bangladesh** remains world's **one of the 117 signatories** and one of **only 20 ratified members).**

8.3.3 Members

- Attend all meetings of the IBC and contribute accordingly;
- Support IBO as and when required;
- Carry out any specific assignment made by the IBC for ensuring Biosafety and Biosecurity.

Appendix 9
Core Working Group of IEDCR

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Dr. Ahmed Nawsher Alam
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Appendix 10

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